

## SUBCHAPTER A—GENERAL PROVISIONS

### PART 1 [RESERVED]

### PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

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AUTHORITY: Sec. 408 of Pub. L. 92-255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub. L. 93-282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94-237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94-581, 90 Stat. 2852; sec. 509 of Pub. L. 96-88, 93 Stat. 695; sec. 973(d) of Pub. L. 97-35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98-24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290ee-3) and sec. 333 of Pub. L. 91-616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93-282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94-581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98-24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290dd-3), as amended by sec. 131 of Pub. L. 102-321, 106 Stat. 368, (42 U.S.C. 290dd-2).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

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##### § 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98-24 to section 527 of the Public Health Service Act which is codified

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at 42 U.S.C. 290ee–3. The amended statutory authority is set forth below:

### § 290ee–3. CONFIDENTIALITY OF PATIENT RECORDS.

#### (a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

#### (b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

#### (c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a

patient or to conduct any investigation of a patient.

#### (d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

#### (e) *Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

#### (f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

#### (g) *Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94–581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

## § 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol

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abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98-24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd-3. The amended statutory authority is set forth below:

### §290dd-3. CONFIDENTIALITY OF PATIENT RECORDS

#### (a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

#### (b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to

the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

#### (c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

#### (d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

#### (e) *Armed Forces and Veterans' Administration; interchange of record of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

#### (f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

#### (g) *Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

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### § 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstance exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee-3(f), 42 U.S.C. 290dd-3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers v. United States*, 327 U.S. 614, 621-22, 66 S. Ct. 705, 707-08 (1946)).

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### § 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee-3(f) and 42 U.S.C. 290dd-3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

### § 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

## Subpart B—General Provisions

### § 2.11 Definitions.

For purposes of these regulations:

*Alcohol abuse* means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

*Drug abuse* means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

*Diagnosis* means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

*Disclose or disclosure* means a communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

*Informant* means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official; and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of

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the program for the purpose of reporting the information obtained to the law enforcement agency or official.

*Patient* means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

*Patient identifying information* means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

*Person* means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

*Program* means:

(a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (See § 2.12(e)(1) for examples.)

*Program director* means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to

act as chief executive of the organization.

*Qualified service organization* means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

*Records* means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

*Third party payer* means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

*Treatment* means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

*Undercover agent* means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

[52 FR 21809, June 9, 1987, as amended by 60 FR 22297, May 5, 1995]

### § 2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure*. The restrictions on disclosure in

these regulations apply to any information, whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee-3(c), 42 U.S.C. 290dd-3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance.* An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any de-

partment or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*—(1) *Veterans' Administration.* These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and

those components of the Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

- (i) Within a program or
- (ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

- (i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and
- (ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.* The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information—*(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see § 2.17) or through patient access (see § 2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

- (i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;
- (ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under § 2.12(c)(3); and

(iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with § 2.32 of these regulations.

(e) *Explanation of applicability—*(1) *Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms “patient” and “program” are defined in § 2.11) if the program is federally assisted in any manner described in § 2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as

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providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment. However, these regulations would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or drug abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) *Federal assistance to program required.* If a patient's alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under § 2.12(b), that patient's record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in § 2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by these regulations unless the program itself received Federal assistance as defined by § 2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under § 2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment

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of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987, as amended at 60 FR 22297, May 5, 1995]

### § 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

(c) *Acknowledging the presence of patients; Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgement of the presence of an identified patient in a facility or part of a facility if the



facility is not publicly identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgement does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

#### § 2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term “minor” means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain al-

cohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

#### § 2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors—*(1) *Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the

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guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients*—(1) *Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

## §2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

## §2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under §2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

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(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

## §2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

## §2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of §2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: "Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]"; and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable

after the end of the retention period specified on the label, destroy the records.

#### § 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee-3 and 42 U.S.C. 290dd-3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

#### § 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These “research privilege” statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research

privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

#### § 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon thereafter as the patient is capable of rational communication, each program shall:

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

(3) A statement that information related to a patient’s commission of a crime on the premises of the program or against personnel of the program is not protected.

(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

(5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the

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sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

### CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser *Unless*:

- (1) The patient consents in writing;
- (2) The disclosure is allowed by a court order; or
- (3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd-3 and 42 U.S.C. 290ee-3 for Federal laws and 42 CFR part 2 for Federal regulations.)

(Approved by the Office of Management and Budget under control number 0930-0099)

## § 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regula-

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tions in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

### Subpart C—Disclosures With Patient's Consent

#### § 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

- (1) The specific name or general designation of the program or person permitted to make the disclosure.
- (2) The name or title of the individual or the name of the organization to which disclosure is to be made.
- (3) The name of the patient.
- (4) The purpose of the disclosure.
- (5) How much and what kind of information is to be disclosed.
- (6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.
- (7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

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1. I (name of patient) ☐ Request ☐ Authorize:  
2. (name or general designation of program  
which is to make the disclosure)

3. To disclose: (kind and amount of informa-  
tion to be disclosed)

4. To: (name or title of the person or organi-  
zation to which disclosure is to be made)

5. For (purpose of the disclosure)

6. Date (on which this consent is signed)

7. Signature of patient

8. Signature of parent or guardian (where re-  
quired)

9. Signature of person authorized to sign in  
lieu of the patient (where required)

10. This consent is subject to revocation at  
any time except to the extent that the pro-  
gram which is to make the disclosure has al-  
ready taken action in reliance on it. If not  
previously revoked, this consent will termi-  
nate upon: (specific date, event, or condi-  
tion)

(c) *Expired, deficient, or false consent.*  
A disclosure may not be made on the  
basis of a consent which:

- (1) Has expired;
- (2) On its face substantially fails to  
conform to any of the requirements set  
forth in paragraph (a) of this section;
- (3) Is known to have been revoked; or
- (4) Is known, or through a reasonable  
effort could be known, by the person  
holding the records to be materially  
false.

(Approved by the Office of Management and  
Budget under control number 0930-0099)

### § 2.32 Prohibition on redisclosure.

*Notice to accompany disclosure.* Each  
disclosure made with the patient's  
written consent must be accompanied  
by the following written statement:

This information has been disclosed to you  
from records protected by Federal confiden-  
tiality rules (42 CFR part 2). The Federal  
rules prohibit you from making any further  
disclosure of this information unless further  
disclosure is expressly permitted by the writ-  
ten consent of the person to whom it per-  
tains or as otherwise permitted by 42 CFR  
part 2. A general authorization for the re-  
lease of medical or other information is NOT  
sufficient for this purpose. The Federal rules  
restrict any use of the information to crimi-

nally investigate or prosecute any alcohol or  
drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2,  
1987]

### § 2.33 Disclosures permitted with writ- ten consent.

If a patient consents to a disclosure  
of his or her records under § 2.31, a pro-  
gram may disclose those records in ac-  
cordance with that consent to any indi-  
vidual or organization named in the  
consent, except that disclosures to cen-  
tral registries and in connection with  
criminal justice referrals must meet  
the requirements of §§ 2.34 and 2.35, re-  
spectively.

### § 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Definitions.* For purposes of this  
section:

*Central registry* means an organiza-  
tion which obtains from two or more  
member programs patient identifying  
information about individuals applying  
for maintenance treatment or detoxi-  
fication treatment for the purpose of  
avoiding an individual's concurrent en-  
rollment in more than one program.

*Detoxification treatment* means the  
dispensing of a narcotic drug in de-  
creasing doses to an individual in order  
to reduce or eliminate adverse physio-  
logical or psychological effects inci-  
dent to withdrawal from the sustained  
use of a narcotic drug.

*Maintenance treatment* means the dis-  
pensing of a narcotic drug in the treat-  
ment of an individual for dependence  
upon heroin or other morphine-like  
drugs.

*Member program* means a detoxifica-  
tion treatment or maintenance treat-  
ment program which reports patient  
identifying information to a central  
registry and which is in the same State  
as that central registry or is not more  
than 125 miles from any border of the  
State in which the central registry is  
located.

(b) *Restrictions on disclosure.* A pro-  
gram may disclose patient records to a  
central registry or to any detoxifica-  
tion or maintenance treatment pro-  
gram not more than 200 miles away for  
the purpose of preventing the multiple  
enrollment of a patient only if:

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- (1) The disclosure is made when:
  - (i) The patient is accepted for treatment;
  - (ii) The type or dosage of the drug is changed; or
  - (iii) The treatment is interrupted, resumed or terminated.
- (2) The disclosure is limited to:
  - (i) Patient identifying information;
  - (ii) Type and dosage of the drug; and
  - (iii) Relevant dates.
- (3) The disclosure is made with the patient's written consent meeting the requirements of § 2.31, except that:
  - (i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and
  - (ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.
- (c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not re-disclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.
- (d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—
  - (1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and
  - (2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.
- (e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxi-

fication or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

### § 2.35 Disclosures to elements of the criminal justice system which have referred patients.

- (a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:
  - (1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and
  - (2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.
- (b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:
  - (1) The anticipated length of the treatment;
  - (2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and
  - (3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.
- (c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified,

ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

### Subpart D—Disclosures Without Patient Consent

#### § 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:

- (1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;
- (2) The name of the individual making the disclosure;
- (3) The date and time of the disclosure; and
- (4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930-0099)

#### § 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

- (1) Is qualified to conduct the research;
- (2) Has a research protocol under which the patient identifying information:
  - (i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and
  - (ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and
- (3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:
  - (i) The rights and welfare of patients will be adequately protected; and
  - (ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

#### § 2.53 Audit and evaluation activities.

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

- (1) Performs the audit or evaluation activity on behalf of:
  - (i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is

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authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in § 2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in § 2.11, program includes an employee of, or provider of medical

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services under, the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a quality improvement organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(d) *Limitations on disclosure and use.* Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66 of these regulations.

### Subpart E—Court Orders Authorizing Disclosure and Use

#### § 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee-3, 42 U.S.C. 290dd-3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.



(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

**§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.**

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

**§ 2.63 Confidential communications.**

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:

(1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;

(2) The disclosure is necessary in connection with investigation or prosecution

of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or

(3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(b) [Reserved]

**§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.**

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a

manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

**§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.**

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 2.66 is sought with an

order under this section, the person holding the records must be given:

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and

(3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be

represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

**§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.**

(a) *Application.* (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless

the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 2.31 of these regulations) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of § 2.64 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information:* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65 of these regulations.

**§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.**

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under § 2.65 of these regulations.

## PART 2a—PROTECTION OF IDENTITY—RESEARCH SUBJECTS

### Sec.

2a.1 Applicability.

2a.2 Definitions.

2a.3 Application; coordination.

2a.4 Contents of application; in general.

2a.5 Contents of application; research projects in which drugs will be administered.

2a.6 Issuance of Confidentiality Certificates; single project limitation.

2a.7 Effect of Confidentiality Certificate.

2a.8 Termination.

AUTHORITY: Sec. 3(a), Pub. L. 91–513 as amended by sec. 122(b), Pub. L. 93–282; 84 Stat. 1241 (42 U.S.C. 242a(a)), as amended by 88 Stat. 132.

SOURCE: 44 FR 20384, Apr. 4, 1979, unless otherwise noted.

### § 2a.1 Applicability.

(a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) provides that “[t]he Secretary [of Health and Human Services] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.” The regulations in this part establish procedures under which any person engaged in research on mental health including research on the use and effect of alcohol and other psychoactive drugs (whether or not the research is federally funded) may, subject to the exceptions set forth in paragraph (b) of this section, apply for such an authorization of confidentiality.

(b) These regulations do not apply to:

(1) Authorizations of confidentiality for research requiring an Investigational New Drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or to approved new drugs, such as methadone, requiring continuation of long-

term studies, records, and reports. Attention is called to 21 CFR 291.505(g) relating to authorizations of confidentiality for patient records maintained by methadone treatment programs.

(2) Authorizations of confidentiality for research which are related to law enforcement activities or otherwise within the purview of the Attorney General's authority to issue authorizations of confidentiality pursuant to section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)) and 21 CFR 1316.21.

(c) The Secretary's regulations on confidentiality of alcohol and drug abuse patient records (42 CFR part 2) and the regulations of this part may, in some instances, concurrently cover the same transaction. As explained in 42 CFR 2.24 and 2.24-1, 42 CFR part 2 restricts voluntary disclosures of information from applicable patient records while a Confidentiality Certificate issued pursuant to the regulations of this part protects a person engaged in applicable research from being compelled to disclose identifying characteristics of individuals who are the subject of such research.

#### § 2a.2 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(b) *Person* means any individual, corporation, government, or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(c) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations.

(d) *Drug* has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(e) *Controlled drug* means a drug which is included in schedule I, II, III, IV, or V of part B of the Controlled Substances Act (21 U.S.C. 811-812).

(f) *Administer* refers to the direct application of a drug to the body of a human research subject, whether such application be by injection, inhalation, ingestion, or any other means, by (1) a qualified person engaged in research (or, in his or her presence, by his or her authorized agent), or (2) a research subject in accordance with instructions of a qualified person engaged in research, whether or not in the presence of a qualified person engaged in research.

(g) *Identifying characteristics* refers to the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.

(h) *Psychoactive drug* means, in addition to alcohol, any drug which has as its principal action an effect on thought, mood, or behavior.

#### § 2a.3 Application; coordination.

(a) Any person engaged in (or who intends to engage in) the research to which this part applies, who desires authorization to withhold the names and other identifying characteristics of individuals who are the subject of such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director, National Institute on Drug Abuse, the Office of the Director, National Institute of Mental Health, or the Office of the Director, National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Maryland 20857 for an authorization of confidentiality.

(b) If there is uncertainty with regard to which Institute is appropriate or if the research project falls within the purview of more than one Institute, an application need be submitted only to one Institute. Persons who are uncertain with regard to the applicability of these regulations to a particular type of research may apply for an authorization of confidentiality under the regulations of this part to one of the Institutes. Requests which are within the scope of the authorities described

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in § 2a.1(b) will be forwarded to the appropriate agency for consideration and the person will be advised accordingly.

(c) An application may accompany, precede, or follow the submission of a request for DHHS grant or contract assistance, though it is not necessary to request DHHS grant or contract assistance in order to apply for a Confidentiality Certificate. If a person has previously submitted any information required in this part in connection with a DHHS grant or contract, he or she may substitute a copy of information thus submitted, if the information is current and accurate. If a person requests a Confidentiality Certificate at the same time he or she submits an application for DHHS grant or contract assistance, the application for a Confidentiality Certificate may refer to the pertinent section(s) of the DHHS grant or contract application which provide(s) the information required to be submitted under this part. (See §§ 2a.4 and 2a.5.)

(d) A separate application is required for each research project for which an authorization of confidentiality is requested.

### § 2a.4 Contents of application; in general.

In addition to any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project shall contain:

(a) The name and address of the individual primarily responsible for the conduct of the research and the sponsor or institution with which he or she is affiliated, if any. Any application from a person affiliated with an institution will be considered only if it contains or is accompanied by documentation of institutional approval. This documentation may consist of a written statement signed by a responsible official of the institution or of a copy of or reference to a valid certification submitted in accordance with 45 CFR part 46.

(b) The location of the research project and a description of the facilities available for conducting the research, including the name and address of any hospital, institution, or clinical

laboratory facility to be utilized in connection with the research.

(c) The names, addresses, and summaries of the scientific or other appropriate training and experience of all personnel having major responsibilities in the research project and the training and experience requirements for major positions not yet filled.

(d) An outline of the research protocol for the project including a clear and concise statement of the purpose and rationale of the research project and the general research methods to be used.

(e) The date on which research will begin or has begun and the estimated date for completion of the project.

(f) A specific request, signed by the individual primarily responsible for the conduct of the research, for authority to withhold the names and other identifying characteristics of the research subjects and the reasons supporting such request.

(g) An assurance (1) From persons making application for a Confidentiality Certificate for a research project for which DHHS grant or contract support is received or sought that they will comply with all the requirements of 45 CFR part 46, "Protection of Human Subjects," or

(2) From all other persons making application that they will comply with the informed consent requirements of 45 CFR 46.103(c) and document legally effective informed consent in a manner consistent with the principles stated in 45 CFR 46.110, if it is determined by the Secretary, on the basis of information submitted by the person making application, that subjects will be placed at risk. If a modification of paragraphs (a) or (b) of 45 CFR 46.110 is to be used, as permitted under paragraph (c) of that section, the applicant will describe the proposed modification and submit it for approval by the Secretary.

(h) An assurance that if an authorization of confidentiality is given it will not be represented as an endorsement of the research project by the Secretary or used to coerce individuals to participate in the research project.

(i) An assurance that any person who is authorized by the Secretary to protect the privacy of research subjects

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will use that authority to refuse to disclose identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects.

(j) An assurance that all research subjects who participate in the project during the period the Confidentiality Certificate is in effect will be informed that:

(1) A Confidentiality Certificate has been issued;

(2) The persons authorized by the Confidentiality Certificate to protect the identity of research subjects may not be compelled to identify research subjects in any civil, criminal, administrative, legislative, or other proceedings whether Federal, State, or local;

(3) If any of the following conditions exist the Confidentiality Certificate does not authorize any person to which it applies to refuse to reveal identifying information concerning research subjects:

(i) The subject consents in writing to disclosure of identifying information,

(ii) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or regulations promulgated thereunder (title 21, Code of Federal Regulations), or

(iii) Authorized personnel of DHHS request identifying information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See § 2a.7(b));

(4) The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects;

(5) The Confidentiality Certificate does not represent an endorsement of the research project by the Secretary.

(k) An assurance that all research subjects who enter the project after the termination of the Confidentiality Certificate will be informed that the authorization of confidentiality has ended and that the persons authorized to protect the identity of research subjects by the Confidentiality Certificate may not rely on the Certificate to

refuse to disclose identifying characteristics of research subjects who were not participants in the project during the period the Certificate was in effect. (See § 2a.8(c)).

### **§ 2a.5 Contents of application; research projects in which drugs will be administered.**

(a) In addition to the information required by § 2a.4 and any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project which involves the administering of a drug shall contain:

(1) Identification of the drugs to be administered in the research project and a description of the methods for such administration, which shall include a statement of the dosages to be administered to the research subjects;

(2) Evidence that individuals who administer drugs are authorized to do so under applicable Federal and State law; and

(3) In the case of a controlled drug, a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

(b) An application for an authorization of confidentiality with respect to a research project which involves the administering of a controlled drug may include a request for exemption of persons engaged in the research from State or Federal prosecution for possession, distribution, and dispensing of controlled drugs as authorized under section 502(d) of the Controlled Substances Act (21 U.S.C. 872(d)) and 21 CFR 1316.22. If the request is in such form, and is supported by such information, as is required by 21 CFR 1316.22, the Secretary will forward it, together with his or her recommendation that such request be approved or disapproved, for the consideration of the Administrator of the Drug Enforcement Administration.

### **§ 2a.6 Issuance of Confidentiality Certificates; single project limitation.**

(a) In reviewing the information provided in the application for a Confidentiality Certificate, the Secretary will take into account:

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(1) The scientific or other appropriate training and experience of all personnel having major responsibilities in the research project;

(2) Whether the project constitutes bona fide “research” which is within the scope of the regulations of this part; and

(3) Such other factors as he or she may consider necessary and appropriate. All applications for Confidentiality Certificates shall be evaluated by the Secretary through such officers and employees of the Department and such experts or consultants engaged for this purpose as he or she determines to be appropriate.

(b) After consideration and evaluation of an application for an authorization of confidentiality, the Secretary will either issue a Confidentiality Certificate or a letter denying a Confidentiality Certificate, which will set forth the reasons for such denial, or will request additional information from the person making application. The Confidentiality Certificate will include:

(1) The name and address of the person making application;

(2) The name and address of the individual primarily responsible for conducting the research, if such individual is not the person making application;

(3) The location of the research project;

(4) A brief description of the research project;

(5) A statement that the Certificate does not represent an endorsement of the research project by the Secretary;

(6) The Drug Enforcement Administration registration number for the project, if any; and

(7) The date or event upon which the Confidentiality Certificate becomes effective, which shall not be before the later of either the commencement of the research project or the date of issuance of the Certificate, and the date or event upon which the Certificate will expire.

(c) A Confidentiality Certificate is not transferable and is effective only with respect to the names and other identifying characteristics of those individuals who are the subjects of the single research project specified in the Confidentiality Certificate. The recipient of a Confidentiality Certificate

shall, within 15 days of any completion or discontinuance of the research project which occurs prior to the expiration date set forth in the Certificate, provide written notification to the Director of the Institute to which application was made. If the recipient determines that the research project will not be completed by the expiration date set forth in the Confidentiality Certificate he or she may submit a written request for an extension of the expiration date which shall include a justification for such extension and a revised estimate of the date for completion of the project. Upon approval of such a request, the Secretary will issue an amended Confidentiality Certificate.

(d) The protection afforded by a Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate (e.g., changes in the personnel having major responsibilities in the research project, major changes in the scope or direction of the research protocol, or changes in the drugs to be administered and the persons who will administer them). The recipient of a Confidentiality Certificate shall notify the Director of the Institute to which application was made of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application. On the basis of such application and other pertinent information the Secretary will either:

(1) Approve the amended application and issue an amended Confidentiality Certificate together with a Notice of Cancellation terminating original the Confidentiality Certificate in accordance with §2a.8; or

(2) Disapprove the amended application and notify the applicant in writing that adoption of the proposed significant changes will result in the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with §2a.8.

### §2a.7 Effect of Confidentiality Certificate.

(a) A Confidentiality Certificate authorizes the withholding of the names and other identifying characteristics of



individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances:

(1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information,

(2) Authorized personnel of DHHS request such information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 for confidentiality standards imposed on such DHHS personnel), or

(3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

#### **§ 2a.8 Termination.**

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project

has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See § 2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

### **PART 3—PATIENT SAFETY ORGANIZATIONS AND PATIENT SAFETY WORK PRODUCT**

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AUTHORITY: 42 U.S.C. 216, 299b-21 through 299b-26; 42 U.S.C. 299c-6.

SOURCE: 73 FR 70796, Nov. 21, 2008, unless otherwise noted.

#### Subpart A—General Provisions

### § 3.10 Purpose.

The purpose of this part is to implement the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 *et*

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*seq.*) by adding sections 921 through 926, 42 U.S.C. 299b-21 through 299b-26.

### § 3.20 Definitions.

As used in this part, the terms listed alphabetically below have the meanings set forth as follows:

*Affiliated provider* means, with respect to a provider, a legally separate provider that is the parent organization of the provider, is under common ownership, management, or control with the provider, or is owned, managed, or controlled by the provider.

*AHRQ* stands for the Agency for Healthcare Research and Quality in HHS.

*ALJ* stands for an Administrative Law Judge of HHS.

*Board* means the members of the HHS Departmental Appeals Board, in the Office of the Secretary, which issues decisions in panels of three.

*Bona fide contract* means:

(1) A written contract between a provider and a PSO that is executed in good faith by officials authorized to execute such contract; or

(2) A written agreement (such as a memorandum of understanding or equivalent recording of mutual commitments) between a Federal, State, local, or Tribal provider and a Federal, State, local, or Tribal PSO that is executed in good faith by officials authorized to execute such agreement.

*Complainant* means a person who files a complaint with the Secretary pursuant to § 3.306.

*Component organization* means an entity that:

(1) Is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization); or

(2) Is owned, managed, or controlled by one or more legally separate parent organizations.

*Component PSO* means a PSO listed by the Secretary that is a component organization.

*Confidentiality provisions* means for purposes of subparts C and D, any requirement or prohibition concerning confidentiality established by sections 921 and 922(b)-(d), (g) and (i) of the Public Health Service Act, 42 U.S.C. 299b-21, 299b-22(b)-(d), (g) and (i) and the

provisions, at §§ 3.206 and 3.208, that implement the statutory prohibition on disclosure of identifiable patient safety work product.

*Disclosure* means the release, transfer, provision of access to, or divulging in any other manner of patient safety work product by:

(1) An entity or natural person holding the patient safety work product to another legally separate entity or natural person, other than a workforce member of, or a health care provider holding privileges with, the entity holding the patient safety work product; or

(2) A component PSO to another entity or natural person outside the component PSO and within the legal entity of which the component PSO is a part.

*Entity* means any organization or organizational unit, regardless of whether the organization is public, private, for-profit, or not-for-profit.

*Group health plan* means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (ERISA)) to the extent that the plan provides medical care (as defined in paragraph (2) of section 2791(a) of the Public Health Service Act, including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

*Health insurance issuer* means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in 42 U.S.C. 300gg-91(b)(3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of 29 U.S.C. 1144(b)(2)). This term does not include a group health plan.

*Health maintenance organization* means:

(1) A Federally qualified health maintenance organization (HMO) (as defined in 42 U.S.C. 300e(a));

(2) An organization recognized under State law as a health maintenance organization; or

(3) A similar organization regulated under State law for solvency in the same manner and to the same extent as

such a health maintenance organization.

*HHS* stands for the United States Department of Health and Human Services.

*HIPAA Privacy Rule* means the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), at 45 CFR part 160 and subparts A and E of part 164.

*Identifiable patient safety work product* means patient safety work product that:

(1) Is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in, or are responsible for, activities that are a subject of the work product;

(2) Constitutes individually identifiable health information as that term is defined in the HIPAA Privacy Rule at 45 CFR 160.103; or

(3) Is presented in a form and manner that allows the identification of an individual who in good faith reported information directly to a PSO or to a provider with the intention of having the information reported to a PSO (“reporter”).

*Nonidentifiable patient safety work product* means patient safety work product that is not identifiable patient safety work product in accordance with the nonidentification standards set forth at § 3.212.

*OCR* stands for the Office for Civil Rights in HHS.

*Parent organization* means an organization that: owns a controlling interest or a majority interest in a component organization; has the authority to control or manage agenda setting, project management, or day-to-day operations; or the authority to review and override decisions of a component organization. The component organization may be a provider.

*Patient Safety Act* means the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 *et seq.*) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b-21 through 299b-26.

*Patient safety activities* means the following activities carried out by or on behalf of a PSO or a provider:

- (1) Efforts to improve patient safety and the quality of health care delivery;
- (2) The collection and analysis of patient safety work product;
- (3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- (4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
- (5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
- (6) The provision of appropriate security measures with respect to patient safety work product;
- (7) The utilization of qualified staff; and
- (8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

*Patient safety evaluation system* means the collection, management, or analysis of information for reporting to or by a PSO.

*Patient safety organization (PSO)* means a private or public entity or component thereof that is listed as a PSO by the Secretary in accordance with subpart B. A health insurance issuer or a component organization of a health insurance issuer may not be a PSO. See also the exclusions in § 3.102 of this part.

*Patient safety work product:*

- (1) Except as provided in paragraph (2) of this definition, patient safety work product means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)
  - (i) Which could improve patient safety, health care quality, or health care outcomes; and
  - (A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation

system for reporting to a PSO, and such documentation includes the date the information entered the patient safety evaluation system; or

- (B) Are developed by a PSO for the conduct of patient safety activities; or
- (ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(2)(i) Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.

(ii) Patient safety work product assembled or developed by a provider for reporting to a PSO may be removed from a patient safety evaluation system and no longer considered patient safety work product if:

(A) The information has not yet been reported to a PSO; and

(B) The provider documents the act and date of removal of such information from the patient safety evaluation system.

(iii) Nothing in this part shall be construed to limit information that is not patient safety work product from being:

(A) Discovered or admitted in a criminal, civil or administrative proceeding;

(B) Reported to a Federal, State, local or Tribal governmental agency for public health or health oversight purposes; or

(C) Maintained as part of a provider's recordkeeping obligation under Federal, State, local or Tribal law.

*Person* means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

*Provider* means:

- (1) An individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) A hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office (includes a group practice), long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) A physician, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner;

(2) Agencies, organizations, and individuals within Federal, State, local, or Tribal governments that deliver health care, organizations engaged as contractors by the Federal, State, local, or Tribal governments to deliver health care, and individual health care practitioners employed or engaged as contractors by the Federal State, local, or Tribal governments to deliver health care; or

(3) A parent organization of one or more entities described in paragraph (1)(i) of this definition or a Federal, State, local, or Tribal government unit that manages or controls one or more entities described in paragraphs (1)(i) or (2) of this definition.

*Research* has the same meaning as the term is defined in the HIPAA Privacy Rule at 45 CFR 164.501.

*Respondent* means a provider, PSO, or responsible person who is the subject of a complaint or a compliance review.

*Responsible person* means a person, other than a provider or a PSO, who has possession or custody of identifiable patient safety work product and is subject to the confidentiality provisions.

*Workforce* means employees, volunteers, trainees, contractors, or other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person.

## Subpart B—PSO Requirements and Agency Procedures

### § 3.102 Process and requirements for initial and continued listing of PSOs.

(a) *Eligibility and process for initial and continued listing*—(1) *Submission of certification*. Any entity, except as specified in paragraph (a)(2) of this section, may request from the Secretary an initial or continued listing as a PSO by submitting a completed certification form that meets the requirements of this section, in accordance with § 3.112. An individual with authority to make commitments on behalf of the entity seeking listing will be required to submit contact information for the entity and:

(i) Attest that the entity is not subject to any exclusion in paragraph (a)(2) of this section;

(ii) Provide certifications that the entity meets each requirement for PSOs in paragraph (b) of this section;

(iii) If the entity is a component of another organization, provide the additional certifications that the entity meets the requirements of paragraph (c)(1)(i) of this section;

(iv) If the entity is a component of an excluded entity described in paragraph (a)(2)(ii), provide the additional certifications and information required by paragraph (c)(1)(ii) of this section;

(v) Attest that the entity has disclosed if the Secretary has ever delisted this entity (under its current name or any other) or refused to list the entity or whether any of its officials or senior managers held comparable positions of responsibility in an entity that was denied listing or delisted and, if any of these circumstances apply, submit with its certifications and related disclosures, the name of the entity or entities that the Secretary declined to list or delisted;

(vi) Attest that the PSO will promptly notify the Secretary during its period of listing if it can no longer comply with any of its attestations and the applicable requirements in §§ 3.102(b) and 3.102(c) or if there have been any changes in the accuracy of the information submitted for listing, along with the pertinent changes; and

(vii) Provide other information that the Secretary determines to be necessary to make the requested listing determination.

(2) *Exclusion of certain entities.* The following types of entities may not seek listing as a PSO:

(i) A health insurance issuer; a unit or division of a health insurance issuer; or an entity that is owned, managed, or controlled by a health insurance issuer;

(ii)(A) An entity that accredits or licenses health care providers;

(B) An entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services;

(C) An agent of an entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services; or

(D) An entity that operates a Federal, state, local or Tribal patient safety reporting system to which health care providers (other than members of the entity's workforce or health care providers holding privileges with the entity) are required to report information by law or regulation.

(iii) A component of an entity listed in paragraph (a)(2)(ii) may seek listing as a component PSO subject to the requirements and restrictions of paragraph (c)(1)(ii) of this section.

(3) *Submission of certification for continued listing.* To facilitate a timely Secretarial determination regarding acceptance of its certification for continued listing, a PSO must submit the required certification no later than 75 days before the expiration of a PSO's three-year period of listing.

(b) *Fifteen general PSO certification requirements.* The certifications submitted to the Secretary in accordance with paragraph (a)(1)(ii) of this section must conform to the following 15 requirements:

(1) *Required certification regarding eight patient safety activities—(i) Initial listing.* An entity seeking initial listing as a PSO must certify that it has written policies and procedures in place to perform each of the eight patient safety activities, defined in § 3.20. With respect to paragraphs (5) and (6) in the definition of patient safety activities regarding confidentiality and security,

the policies and procedures must include and provide for:

(A) Compliance with the confidentiality provisions of subpart C of this part and with appropriate security measures as required by § 3.106 of this subpart.

(B) Notification of each provider that submitted patient safety work product or data as described in § 3.108(b)(2) to the entity if the submitted work product or data was subject to an unauthorized disclosure or its security was breached.

(ii) *Continued Listing.* A PSO seeking continued listing must certify that it is performing, and will continue to perform, each of the patient safety activities defined in § 3.20, and is and will continue to comply with the requirements of paragraphs (b)(1)(i)(A) and (B) of this section.

(2) *Required certification regarding seven PSO criteria—(i) Initial Listing.* In its initial certification submission, an entity must also certify that, if listed as a PSO, it will comply with the seven requirements in paragraphs (b)(2)(i)(A) through (G) of this section.

(A) The mission and primary activity of the PSO must be to conduct activities that are to improve patient safety and the quality of health care delivery.

(B) The PSO must have appropriately qualified workforce members, including licensed or certified medical professionals.

(C) The PSO, within the 24-month period that begins on the date of its initial listing as a PSO, and within each sequential 24-month period thereafter, must have 2 bona fide contracts, each of a reasonable period of time, each with a different provider for the purpose of receiving and reviewing patient safety work product.

(D) The PSO is not a health insurance issuer, and is not a component of a health insurance issuer.

(E) The PSO must make disclosures to the Secretary as required under § 3.102(d), in accordance with § 3.112 of this subpart.

(F) To the extent practical and appropriate, the PSO must collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

(G) The PSO must utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

(ii) *Continued Listing.* A PSO seeking continued listing must certify that it is complying with, and will continue to comply with, the requirements of paragraphs (b)(2)(i)(A) through (G) of this section.

(iii) *Compliance with the criterion for collecting patient safety work product in a standardized manner to the extent practical and appropriate.* With respect to paragraph (b)(2)(i)(F) of this section, the Secretary will assess compliance by a PSO in the following manner.

(A) A PSO seeking continued listing must:

(1) Certify that the PSO is using the Secretary's published guidance for common formats and definitions in its collection of patient safety work product (option (I));

(2) Certify that the PSO is using an alternative system of formats and definitions that permits valid comparisons of similar cases among similar providers (option (II)); or

(3) Provide a clear explanation for why it is not practical or appropriate for the PSO to comply with options (I) or (II) at this time.

(B) The Secretary will consider a PSO to be in compliance if the entity complies with option (I), satisfactorily demonstrates that option (II) permits valid comparisons of similar cases among similar providers, or satisfactorily demonstrates that it is not practical or appropriate for the PSO to comply with options (I) or (II) at this time.

(c) *Additional certifications required of component organizations—*(1) *Requirements when seeking listing—*(i) *Requirements that all component organizations must meet.* In addition to meeting the 15 general PSO certification requirements of paragraph (b) of this section, an entity seeking initial listing that is a component of another organization must certify that it will comply with the requirements of paragraph (c)(2) of this section. A component PSO seeking continued listing must certify that it is complying with, and will continue to comply with, the requirements of this

same paragraph (c)(2). At initial and continued listing, a component entity must attach to its certifications for listing contact information for its parent organization(s).

(ii) *Additional requirements and limitations applicable to components of entities that are excluded from listing.* In addition to the requirements under paragraph (c)(1)(i) of this section, a component of an organization excluded from listing under paragraph (a)(2)(ii) of this section must submit the additional certifications and specified information for initial and continued listing and comply with paragraph (c)(4) of this section.

(2) *Required component certifications—*

(i) *Separation of patient safety work product.* A component PSO must maintain patient safety work product separately from the rest of the parent organization(s) of which it is a part, and establish appropriate security measures to maintain the confidentiality of patient safety work product. The information system in which the component PSO maintains patient safety work product must not permit unauthorized access by one or more individuals in, or by units of, the rest of the parent organization(s) of which it is a part.

(ii) *Nondisclosure of patient safety work product.* A component PSO must require that members of its workforce and any other contractor staff not make unauthorized disclosures of patient safety work product to the rest of the parent organization(s) of which it is a part.

(iii) *No conflict of interest.* The pursuit of the mission of a component PSO must not create a conflict of interest with the rest of the parent organization(s) of which it is a part.

(3) *Written agreements for assisting a component PSO in the conduct of patient safety activities.* Notwithstanding the requirements of paragraph (c)(2) of this section, a component PSO may provide access to identifiable patient safety work product to one or more individuals in, or to one or more units of, the rest of the parent organization(s) of which it is a part, if the component PSO enters into a written agreement with such individuals or units which requires that:

(i) The component PSO will only provide access to identifiable patient safety work product to enable such individuals or units to assist the component PSO in its conduct of patient safety activities, and

(ii) Such individuals or units that receive access to identifiable patient safety work product pursuant to such written agreement will only use or disclose such information as specified by the component PSO to assist the component PSO in its conduct of patient safety activities, will take appropriate security measures to prevent unauthorized disclosures and will comply with the other certifications the component has made pursuant to paragraph (c)(2) of this section regarding unauthorized disclosures and conducting the mission of the PSO without creating conflicts of interest.

(4) *Required attestations, information and operational limitations for components of entities excluded from listing.* A component organization of an entity that is subject to the restrictions of paragraph (a)(2)(ii) of this section must:

(i) Submit the following information with its certifications for listing:

(A) A statement describing its parent organization's role, and the scope of the parent organization's authority, with respect to any of the following that apply: Accreditation or licensure of health care providers, oversight or enforcement of statutory or regulatory requirements governing the delivery of health care services, serving as an agent of such a regulatory oversight or enforcement authority, or administering a public mandatory patient safety reporting system;

(B) An attestation that the parent organization has no policies or procedures that would require or induce providers to report patient safety work product to their component organization once listed as a PSO and that the component PSO will notify the Secretary within 5 calendar days of the date on which the component organization has knowledge of the adoption by the parent organization of such policies or procedures, and an acknowledgment that the adoption of such policies or procedures by the parent organization during the component PSO's period of

listing will result in the Secretary initiating an expedited revocation process in accordance with § 3.108(e); and

(C) An attestation that the component organization will prominently post notification on its Web site and publish in any promotional materials for dissemination to providers, a summary of the information that is required by paragraph (c)(4)(i)(A) of this section.

(ii) Comply with the following requirements during its period of listing:

(A) The component organization may not share staff with its parent organization(s).

(B) The component organization may enter into a written agreement pursuant to paragraph (c)(3) but such agreements are limited to units or individuals of the parent organization(s) whose responsibilities do not involve the activities specified in the restrictions in paragraph (a)(2)(ii) of this section.

(d) *Required notifications.* Upon listing, PSOs must meet the following notification requirements:

(1) *Notification regarding PSO compliance with the minimum contract requirement.* No later than 45 calendar days prior to the last day of the pertinent 24-month assessment period, specified in paragraph (b)(2)(iii)(C) of this section, the Secretary must receive from a PSO a certification that states whether it has met the requirement of that paragraph regarding two bona fide contracts, submitted in accordance with § 3.112 of this subpart.

(2) *Notification regarding a PSO's relationships with its contracting providers—*

(i) *Requirement.* A PSO must file a disclosure statement regarding a provider with which it has a contract that provides the confidentiality and privilege protections of the Patient Safety Act (hereinafter referred to as a Patient Safety Act contract) if the PSO has any other relationships with this provider that are described in paragraphs (d)(2)(i)(A) through (D) of this section. The PSO must disclose all such relationships. A disclosure statement is not required if all of its other relationships with the provider are limited to Patient Safety Act contracts.

(A) The provider and PSO have current contractual relationships, other



than those arising from any Patient Safety Act contracts, including formal contracts or agreements that impose obligations on the PSO.

(B) The provider and PSO have current financial relationships other than those arising from any Patient Safety Act contracts. A financial relationship may include any direct or indirect ownership or investment relationship between the PSO and the contracting provider, shared or common financial interests or direct or indirect compensation arrangements whether in cash or in-kind.

(C) The PSO and provider have current reporting relationships other than those arising from any Patient Safety Act contracts, by which the provider has access to information regarding the work and operation of the PSO that is not available to other contracting providers.

(D) Taking into account all relationships that the PSO has with the provider, the PSO is not independently managed or controlled, or the PSO does not operate independently from, the contracting provider.

(ii) *Content.* A PSO must submit to the Secretary the required attestation form for disclosures with the information specified below in accordance with § 3.112 and this section. The substantive information that must be included with each submission has two required parts:

(A) *The Required Disclosures.* The first part of the substantive information must provide a succinct list of obligations between the PSO and the contracting provider apart from their Patient Safety Act contract(s) that create, or contain, any of the types of relationships that must be disclosed based upon the requirements of paragraphs (d)(2)(i)(A) through (D) of this section. Each reportable obligation or discrete set of obligations that the PSO has with this contracting provider should be listed only once; noting the specific aspects of the obligation(s) that reflect contractual or financial relationships, involve access to information that is not available to other providers, or affect the independence of PSO operations, management, or control.

(B) *An Explanatory Narrative.* The second required part of the substantive information must provide a brief explanatory narrative succinctly describing: The policies and procedures that the PSO has in place to ensure adherence to objectivity and professionally recognized analytic standards in the assessments it undertakes; and any other policies or procedures, or agreements with this provider, that the PSO has in place to ensure that it can fairly and accurately perform patient safety activities.

(iii) *Deadlines for submission.* The Secretary must receive a disclosure statement within 45 days of the date on which a PSO enters a contract with a provider if the circumstances described in any of the paragraphs (d)(2)(i)(A) through (D) of this section are met on the date the contract is entered. During the contract period, if these circumstances subsequently arise, the Secretary must receive a disclosure statement from the PSO within 45 days of the date that any disclosure requirement in paragraph (d)(2)(i) of this section first applies.

#### § 3.104 Secretarial actions.

(a) *Actions in response to certification submissions for initial and continued listing as a PSO.* (1) In response to an initial or continued certification submission by an entity, pursuant to the requirements of § 3.102 of this subpart, the Secretary may—

(i) Accept the certification submission and list the entity as a PSO, or maintain the listing of a PSO, if the Secretary determines that the entity meets the applicable requirements of the Patient Safety Act and this subpart;

(ii) Deny acceptance of a certification submission and, in the case of a currently listed PSO, remove the entity from the list if the entity does not meet the applicable requirements of the Patient Safety Act and this subpart; or

(iii) Condition the listing of an entity or the continued listing of a PSO, following a determination made pursuant to paragraph (c) of this section or a determination after review of the pertinent history of an entity that has been

delisted or refused listing and its officials and senior managers.

(2) *Basis for determination.* In making a determination regarding listing, the Secretary will consider the certification submission; any prior actions by the Secretary regarding the entity or PSO including delisting; any history of or current non-compliance by the entity or the PSO or its officials or senior managers with statutory or regulatory requirements or requests from the Secretary; the relationships of the entity or PSO with providers; and any findings made by the Secretary in accordance with paragraph (c) of this section.

(3) *Notification.* The Secretary will notify in writing each entity of action taken on its certification submission for initial or continued listing. The Secretary will provide reasons when an entity's certification is conditionally accepted and the entity is conditionally listed, when an entity's certification is not accepted and the entity is not listed, or when acceptance of its certification is revoked and the entity is delisted.

(b) *Actions regarding PSO compliance with the minimum contract requirement.* After the date on which the Secretary, under § 3.102(d)(1) of this subpart, must receive notification regarding compliance of a PSO with the minimum contract requirement—

(1) If the PSO has met the minimum contract requirement, the Secretary will acknowledge in writing receipt of the notification and add information to the list established pursuant to paragraph (d) of this section stating that the PSO has certified that it has met the requirement.

(2) If the PSO states that it has not yet met the minimum contract requirement by the date specified in § 3.102(d)(1), or if notice is not received by that date, the Secretary will issue to the PSO a notice of a preliminary finding of deficiency as specified in § 3.108(a)(2) and establish a period for correction that extends until midnight of the last day of the PSO's applicable 24-month period of assessment. Thereafter, if the requirement has not been met, the Secretary will provide the PSO a written notice of proposed revocation and delisting in accordance with § 3.108(a)(3).

(c) *Actions regarding required disclosures by PSOs of relationships with contracting providers.* The Secretary will review and make findings regarding each disclosure statement submitted by a PSO, pursuant to § 3.102(d)(2), regarding its relationships with contracting provider(s), determine whether such findings warrant action regarding the listing of the PSO in accordance with paragraph (c)(2) of this section, and make the findings public.

(1) *Basis of findings regarding PSO disclosure statements.* In reviewing disclosure statements, submitted pursuant to § 3.102(d)(2) of this subpart, the Secretary will consider the disclosed relationship(s) between the PSO and the contracting provider and the statements and material submitted by the PSO describing the policies and procedures that the PSO has in place to determine whether the PSO can fairly and accurately perform the required patient safety activities.

(2) *Determination by the Secretary.* Based on the Secretary's review and findings, he may choose to take any of the following actions:

(i) For an entity seeking an initial or continued listing, the Secretary may list or continue the listing of an entity without conditions, list the entity subject to conditions, or deny the entity's certification for initial or continued listing; or

(ii) For a listed PSO, the Secretary may determine that the entity will remain listed without conditions, continue the entity's listing subject to conditions, or remove the entity from the list of PSOs.

(3) *Release of disclosure statements and Secretarial findings.* (i) Subject to paragraph (c)(3)(ii) of this section, the Secretary will make disclosure statements available to the public along with related findings that are made available in accordance with paragraph (c) of this section.

(ii) The Secretary may withhold information that is exempt from public disclosure under the Freedom of Information Act, *e.g.*, trade secrets or confidential commercial information that are subject to the restrictions of 18 U.S.C. 1905.

(d) *Maintaining a list of PSOs.* The Secretary will compile and maintain a

publicly available list of entities whose certifications as PSOs have been accepted. The list will include contact information for each entity, a copy of all certification forms and disclosure statements submitted by each entity in accordance with paragraph (c)(3)(ii) of this section, the effective date of the PSO's listing, and information on whether a PSO has certified that it has met the two contract requirement. The list also will include a copy of the Secretary's findings regarding each disclosure statement submitted by an entity, information describing any related conditions that have been placed by the Secretary on the listing of an entity as a PSO, and other information that this Subpart states may be made public. AHRQ may maintain a PSO website (or a comparable future form of public notice) and may post the list on this website.

(e) *Three-year period of listing.* (1) The three-year period of listing of a PSO will automatically expire at midnight of the last day of this period, unless the listing had been revoked or relinquished earlier in accordance with § 3.108 of this subpart, or if, prior to this automatic expiration, the PSO seeks a new three-year listing, in accordance with § 3.102, and the Secretary accepts the PSO's certification for a new three-year listing, in accordance with § 3.104(a).

(2) The Secretary plans to send a written notice of imminent expiration to a PSO at least 60 calendar days prior to the date on which its three-year period of listing expires if the Secretary has not yet received a certification for continued listing. The Secretary plans to indicate, on the AHRQ PSO website, the PSOs from whom certifications for continued listing have not been timely received.

(f) *Effective dates of Secretarial actions.* Unless otherwise stated, the effective date of each action by the Secretary pursuant to this subpart will be specified in the written notice of such action that is sent to the entity. When the Secretary sends a notice that addresses acceptance or revocation of an entity's certifications or voluntary relinquishment by an entity of its status as a PSO, the notice will specify the ef-

fective date and time of listing or delisting.

### § 3.106 Security requirements.

(a) *Application.* A PSO must secure patient safety work product in conformance with the security requirements of paragraph (b) of this section. These requirements must be met at all times and at any location at which the PSO, its workforce members, or its contractors receive, access, or handle patient safety work product. Handling patient safety work product includes its processing, development, use, maintenance, storage, removal, disclosure, transmission and destruction.

(b) *Security framework.* A PSO must have written policies and procedures that address each of the considerations specified in this subsection. In addressing the framework that follows, the PSO may develop appropriate and scalable security standards, policies, and procedures that are suitable for the size and complexity of its organization.

(1) *Security management.* A PSO must address:

(i) Maintenance and effective implementation of written policies and procedures that conform to the requirements of this section to protect the confidentiality, integrity, and availability of the patient safety work product that is received, accessed, or handled; and to monitor and improve the effectiveness of such policies and procedures, and

(ii) Training of the PSO workforce and PSO contractors who receive, access, or handle patient safety work product regarding the requirements of the Patient Safety Act, this Part, and the PSO's policies and procedures regarding the confidentiality and security of patient safety work product.

(2) *Distinguishing patient safety work product.* A PSO must address:

(i) Maintenance of the security of patient safety work product, whether in electronic or other media, through either physical separation from non-patient safety work product, or if co-located with non-patient safety work product, by making patient safety work product distinguishable so that the appropriate form and level of security can be applied and maintained;

(ii) Protection of the media, whether in electronic, paper, or other media or format, that contain patient safety work product, limiting access to authorized users, and sanitizing and destroying such media before their disposal or release for reuse; and

(iii) Physical and environmental protection, to control and limit physical and virtual access to places and equipment where patient safety work product is received, accessed, or handled.

(3) *Security control and monitoring.* A PSO must address:

(i) Identification of those authorized to receive, access, or handle patient safety work product and an audit capacity to detect unlawful, unauthorized, or inappropriate receipt, access, or handling of patient safety work product, and

(ii) Methods to prevent unauthorized receipt, access, or handling of patient safety work product.

(4) *Security assessment.* A PSO must address:

(i) Periodic assessments of security risks and controls to establish if its controls are effective, to correct any deficiency identified, and to reduce or eliminate any vulnerabilities.

(ii) System and communications protection, to monitor, control, and protect PSO receipt, access, or handling of patient safety work product with particular attention to the transmission of patient safety work product to and from providers, other PSOs, contractors or any other responsible persons.

**§ 3.108 Correction of deficiencies, revocation, and voluntary relinquishment.**

(a) *Process for correction of a deficiency and revocation*—(1) *Circumstances leading to revocation.* The Secretary may revoke his acceptance of an entity's certification ("revocation") and delist the entity as a PSO if he determines—

(i) The PSO is not fulfilling the certifications made to the Secretary as required by § 3.102;

(ii) The PSO has not met the two contract requirement, as required by § 3.102(d)(1);

(iii) Based on a PSO's disclosures made pursuant to § 3.102(d)(2), that the entity cannot fairly and accurately perform the patient safety activities of

a PSO with a public finding to that effect; or

(iv) The PSO is not in compliance with any other provision of the Patient Safety Act or this part.

(2) *Notice of preliminary finding of deficiency and establishment of an opportunity for correction of a deficiency.* (i) Except as provided by paragraph (e) of this section, if the Secretary determines that a PSO is not in compliance with its obligations under the Patient Safety Act or this subpart, the Secretary must send a PSO written notice of the preliminary finding of deficiency. The notice must state the actions or inactions that encompass the deficiency finding, outline the evidence that the deficiency exists, specify the possible and/or required corrective actions that must be taken, and establish a date by which the deficiency must be corrected. The Secretary may specify in the notice the form of documentation required to demonstrate that the deficiency has been corrected.

(ii) The notice of a preliminary finding of deficiency is presumed received five days after it is sent, absent evidence of the actual receipt date. If a PSO does not submit evidence to the Secretary within 14 calendar days of actual or constructive receipt of such notice, whichever is longer, which demonstrates that the preliminary finding is factually incorrect, the preliminary finding will be the basis for a finding of deficiency.

(3) *Determination of correction of a deficiency.* (i) Unless the Secretary specifies another date, the Secretary must receive documentation to demonstrate that the PSO has corrected any deficiency cited in the preliminary finding of deficiency no later than five calendar days following the last day of the correction period that is specified by the Secretary in such notice.

(ii) In making a determination regarding the correction of any deficiency, the Secretary will consider the documentation submitted by the PSO, any assessments under § 3.110, recommendations of program staff, and any other information available regarding the PSO that the Secretary deems appropriate and relevant to the PSO's implementation of the terms of its certification.

(iii) After completing his review, the Secretary may make one of the following determinations:

(A) The action(s) taken by the PSO have corrected any deficiency, in which case the Secretary will withdraw the notice of deficiency and so notify the PSO;

(B) The PSO has acted in good faith to correct the deficiency, but the Secretary finds an additional period of time is necessary to achieve full compliance and/or the required corrective action specified in the notice of a preliminary finding of deficiency needs to be modified in light of the experience of the PSO in attempting to implement the corrective action, in which case the Secretary will extend the period for correction and/or modify the specific corrective action required; or

(C) The PSO has not completed the corrective action because it has not acted with reasonable diligence or speed to ensure that the corrective action was completed within the allotted time, in which case the Secretary will issue to the PSO a notice of proposed revocation and delisting.

(iv) When the Secretary issues a written notice of proposed revocation and delisting, the notice will specify the deficiencies that have not been timely corrected and will detail the manner in which the PSO may exercise its opportunity to be heard in writing to respond to the deficiencies specified in the notice.

(4) *Opportunity to be heard in writing following a notice of proposed revocation and delisting.* The Secretary will afford a PSO an opportunity to be heard in writing, as specified in paragraph (a)(4)(i) of this section, to provide a substantive response to the deficiency finding(s) set forth in the notice of proposed revocation and delisting.

(i) The notice of proposed revocation and delisting is presumed received five days after it is sent, absent evidence of actual receipt. The Secretary will provide a PSO with a period of time, beginning with the date of receipt of the notice of proposed revocation and delisting of which there is evidence, or the presumed date of receipt if there is no evidence of earlier receipt, and ending at midnight 30 calendar days thereafter, during which the PSO may sub-

mit a substantive response to the deficiency findings in writing.

(ii) The Secretary will provide to the PSO any rules of procedure governing the form or transmission of the written response to the notice of proposed revocation and delisting. Such rules may also be posted on the AHRQ PSO Web site or published in the FEDERAL REGISTER.

(iii) If a PSO does not submit a written response to the deficiency finding(s) within 30 calendar days of receipt of the notice of proposed revocation and delisting, the notice of proposed revocation becomes final as a matter of law and the basis for Secretarial action under paragraph (b)(1) of this section.

(5) *The Secretary's decision regarding revocation.* The Secretary will review the entire administrative record pertaining to a notice of proposed revocation and delisting and any written materials submitted by the PSO under paragraph (a)(4) of this section. The Secretary may affirm, reverse, or modify the notice of proposed revocation and delisting and will make a determination with respect to the continued listing of the PSO.

(b) *Revocation of the Secretary's acceptance of a PSO's certifications—(1) Establishing the date and time of revocation and delisting.* When the Secretary concludes, in accordance with a decision made under paragraphs (a)(5), (e)(3)(iii) or (e)(3)(iv)(C) of this section, that revocation of the acceptance of a PSO's certification is warranted for its failure to comply with requirements of the Patient Safety Act or of this Part, the Secretary will establish the effective time and date for such prompt revocation and removal of the entity from the list of PSOs, so notify the PSO in writing, and provide the relevant public notice required by § 3.108(d) of this subpart.

(2) *Required notification of providers and status of data.* (i) Upon being notified of the Secretary's action pursuant to paragraph (b)(1) of this section, the former PSO will take all reasonable actions to notify each provider, whose patient safety work product it collected

or analyzed, of the Secretary's action(s) and the following statutory information: Confidentiality and privilege protections that applied to patient safety work product while the former PSO was listed continue to apply after the entity is removed from listing. Data submitted by providers to the former PSO for 30 calendar days following the date and time on which the entity was removed from the list of PSOs pursuant to paragraph (b)(1) of this section will have the same status as data submitted while the entity was still listed.

(ii) Within 15 days of being notified of the Secretary's action pursuant to paragraph (b)(1) of this section, the former PSO shall submit to the Secretary confirmation that it has taken the actions in paragraph (b)(2)(i) of this section.

(3) *Disposition of patient safety work product and data.* Within 90 days following the effective date of revocation and delisting pursuant to paragraph (b)(1) of this section, the former PSO will take one or more of the following measures in regard to patient safety work product and data described in paragraph (b)(2)(i) of this section:

(i) Transfer such patient safety work product or data, with the approval of the source from which it was received, to a PSO that has agreed to receive such patient safety work product or data;

(ii) Return such work product or data to the source from which it was submitted; or

(iii) If returning such patient safety work product or data to its source is not practicable, destroy such patient safety work product or data.

(c) *Voluntary relinquishment*—(1) *Circumstances constituting voluntary relinquishment.* A PSO will be considered to have voluntarily relinquished its status as a PSO if the Secretary accepts a notification from a PSO that it wishes to relinquish voluntarily its listing as a PSO.

(2) *Notification of voluntary relinquishment.* A PSO's notification of voluntary relinquishment to the Secretary must include the following:

(i) An attestation that all reasonable efforts have been made, or will have been made by a PSO within 15 calendar

days of this statement, to notify the sources from which it received patient safety work product of the PSO's intention to cease PSO operations and activities, to relinquish voluntarily its status as a PSO, to request that these other entities cease reporting or submitting any further information to the PSO as soon as possible, and inform them that any information reported after the effective date and time of delisting that the Secretary sets pursuant to paragraph (c)(3) of this section will not be protected as patient safety work product under the Patient Safety Act.

(ii) An attestation that the entity has established a plan, or within 15 calendar days of this statement, will have made all reasonable efforts to establish a plan, in consultation with the sources from which it received patient safety work product, that provides for the disposition of the patient safety work product held by the PSO consistent with, to the extent practicable, the statutory options for disposition of patient safety work product as set out in paragraph (b)(3) of this section; and

(iii) Appropriate contact information for further communications from the Secretary.

(3) *Response to notification of voluntary relinquishment.* (i) After a PSO provides the notification required by paragraph (c)(2) of this section, the Secretary will respond in writing to the entity indicating whether the proposed voluntary relinquishment of its PSO status is accepted. If the voluntary relinquishment is accepted, the Secretary's response will indicate an effective date and time for the entity's removal from the list of PSOs and will provide public notice of the voluntary relinquishment and the effective date and time of the delisting, in accordance with § 3.108(d) of this subpart.

(ii) If the Secretary receives a notification of voluntary relinquishment during or immediately after revocation proceedings for cause under paragraphs (a)(4) and (a)(5) of this section, the Secretary, as a matter of discretion, may accept voluntary relinquishment in accordance with the preceding paragraph or decide not to accept the entity's proposed voluntary relinquishment and proceed with the revocation for cause

and delisting pursuant to paragraph (b)(1) of this section.

(4) *Non-applicability of certain procedures and requirements.* (i) A decision by the Secretary to accept a request by a PSO to relinquish voluntarily its status as a PSO pursuant to paragraph (c)(2) of this section does not constitute a determination of a deficiency in PSO compliance with the Patient Safety Act or with this Subpart.

(ii) The procedures and requirements of §3.108(a) of this subpart regarding deficiencies including the opportunity to correct deficiencies and to be heard in writing, and the procedures and requirements of §3.108(b) are not applicable to determinations of the Secretary made pursuant to this subsection.

(d) *Public notice of delisting regarding removal from listing.* If the Secretary removes an entity from the list of PSOs following revocation of acceptance of the entity's certification pursuant to §3.108(b)(1), voluntary relinquishment pursuant to §3.108(c)(3), or expiration of an entity's period of listing pursuant to §3.104(e)(1), the Secretary will promptly publish in the FEDERAL REGISTER and on the AHRQ PSO website, or in a comparable future form of public notice, a notice of the actions taken and the effective dates.

(e) *Expedited revocation and delisting—* (1) *Basis for expedited revocation.* Notwithstanding any other provision of this section, the Secretary may use the expedited revocation process described in paragraph (e)(3) of this section if he determines—

(i) The PSO is not in compliance with this part because it is or is about to become an entity described in §3.102(a)(2).

(ii) The parent organization of the PSO is an entity described in §3.102(a)(2) and requires or induces health care providers to report patient safety work product to its component PSO; or

(iii) The circumstances for revocation in paragraph (a)(1) of this section exist, and the Secretary has determined that there would be serious adverse consequences if the PSO were to remain listed.

(2) *Applicable provisions.* If the Secretary uses the expedited revocation process described in paragraph (e)(3) of this section, the procedures in para-

graphs (a)(2) through (5) of this section shall not apply and paragraph (a)(1) and paragraphs (b) and (d) of this section shall apply.

(3) *Expedited revocation process.* (i) The Secretary must send the PSO a written notice of deficiency that:

(A) Identifies the evidence that the circumstances for revocation and delisting under paragraph (a)(1) of this section exist, and any corrective action that the PSO must take if the Secretary determines that corrective action may resolve the matter so that the entity would not be delisted; and

(B) Provides an opportunity for the PSO to respond in writing to correct the facts or the legal bases for delisting found in the notice, and to offer any other grounds for its not being delisted.

(ii) The notice of deficiency will be presumed to be received five days after it is sent, absent evidence of the actual receipt date.

(iii) If the PSO does not submit a written response to the Secretary within 14 calendar days of actual or constructive receipt of such notice, whichever is longer, the Secretary may revoke his acceptance of the PSO's certifications and remove the entity from the list of PSOs.

(iv) If the PSO responds in writing within the required 14-day time period, the Secretary may take any of the following actions:

(A) Withdraw the notice of deficiency;

(B) Provide the PSO with more time to resolve the matter to the Secretary's satisfaction; or

(C) Revoke his acceptance of the PSO's certifications and remove the entity from the list of PSOs.

### §3.110 Assessment of PSO compliance.

The Secretary may request information or conduct announced or unannounced reviews of, or site visits to, PSOs, to assess or verify PSO compliance with the requirements of this subpart and for these purposes will be allowed to inspect the physical or virtual sites maintained or controlled by the PSO. The Secretary will be allowed to inspect and/or be given or sent copies of any PSO records deemed necessary

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and requested by the Secretary to implement the provisions of this subpart. Such PSO records may include patient safety work product in accordance with § 3.206(d) of this part.

#### § 3.112 Submissions and forms.

(a) Forms referred to in this subpart may be obtained on the PSO Web site (<http://www.pso.ahrq.gov>) maintained for the Secretary by AHRQ or a successor agency or on successor publication technology or by requesting them in writing by e-mail at [psa@ahrq.hhs.gov](mailto:psa@ahrq.hhs.gov), or by mail from the Agency for Healthcare Research and Quality, CQuIPS, PSO Liaison, 540 Gaither Road, Rockville, MD 20850. A form (including any required attachments) must be submitted in accordance with the accompanying instructions.

(b) Information submitted to AHRQ in writing, but not required to be on or attached to a form, and requests for information from AHRQ, may be submitted by mail or other delivery to the Agency for Healthcare Research and Quality, CQuIPS, PSO Liaison, 540 Gaither Road, Rockville, MD 20850, by facsimile at (301) 427–1341, or by e-mail at [psa@ahrq.hhs.gov](mailto:psa@ahrq.hhs.gov).

(c) If a submission to the Secretary is incomplete or additional information is needed to allow a determination to be made under this subpart, the submitter will be notified if any additional information is required.

### Subpart C—Confidentiality and Privilege Protections of Patient Safety Work Product

#### § 3.204 Privilege of patient safety work product.

(a) *Privilege.* Notwithstanding any other provision of Federal, State, local, or Tribal law and subject to paragraph (b) of this section and § 3.208 of this subpart, patient safety work product shall be privileged and shall not be:

(1) Subject to a Federal, State, local, or Tribal civil, criminal, or administrative subpoena or order, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a provider;

(2) Subject to discovery in connection with a Federal, State, local, or Tribal

civil, criminal, or administrative proceeding, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a provider;

(3) Subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, local, or Tribal law;

(4) Admitted as evidence in any Federal, State, local, or Tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) *Exceptions to privilege.* Privilege shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) Disclosure of relevant patient safety work product for use in a criminal proceeding, subject to the conditions at § 3.206(b)(1) of this subpart.

(2) Disclosure to the extent required to permit equitable relief subject to the conditions at § 3.206(b)(2) of this subpart.

(3) Disclosure pursuant to provider authorizations subject to the conditions at § 3.206(b)(3) of this subpart.

(4) Disclosure of non-identifiable patient safety work product subject to the conditions at § 3.206(b)(5) of this subpart.

(c) *Implementation and enforcement by the Secretary.* Privilege shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance, or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

#### § 3.206 Confidentiality of patient safety work product.

(a) *Confidentiality.* Subject to paragraphs (b) through (e) of this section,



and §§ 3.208 and 3.210 of this subpart, patient safety work product shall be confidential and shall not be disclosed.

(b) *Exceptions to confidentiality.* The confidentiality provisions shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) *Disclosure in criminal proceedings.* Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in-camera determination that:

(i) Such patient safety work product contains evidence of a criminal act;

(ii) Such patient safety work product is material to the proceeding; and

(iii) Such patient safety work product is not reasonably available from any other source.

(2) *Disclosure to permit equitable relief for reporters.* Disclosure of patient safety work product to the extent required to permit equitable relief under section 922 (f)(4)(A) of the Public Health Service Act, provided the court or administrative tribunal has issued a protective order to protect the confidentiality of the patient safety work product in the course of the proceeding.

(3) *Disclosure authorized by identified providers.* (i) Disclosure of identifiable patient safety work product consistent with a valid authorization if such authorization is obtained from each provider identified in such work product prior to disclosure. A valid authorization must:

(A) Be in writing and signed by the provider from whom authorization is sought; and

(B) Contain sufficient detail to fairly inform the provider of the nature and scope of the disclosures being authorized;

(ii) A valid authorization must be retained by the disclosing entity for six years from the date of the last disclosure made in reliance on the authorization and made available to the Secretary upon request.

(4) *Disclosure for patient safety activities—(i) Disclosure between a provider and a PSO.* Disclosure of patient safety work product for patient safety activities by a provider to a PSO or by a PSO to that disclosing provider.

(ii) *Disclosure to a contractor of a provider or a PSO.* A provider or a PSO

may disclose patient safety work product for patient safety activities to an entity with which it has contracted to undertake patient safety activities on its behalf. A contractor receiving patient safety work product for patient safety activities may not further disclose patient safety work product, except to the provider or PSO with which it is contracted.

(iii) *Disclosure among affiliated providers.* Disclosure of patient safety work product for patient safety activities by a provider to an affiliated provider.

(iv) *Disclosure to another PSO or provider.* Disclosure of patient safety work product for patient safety activities by a PSO to another PSO or to another provider that has reported to the PSO, or, except as otherwise permitted in paragraph (b)(4)(iii) of this section, by a provider to another provider, provided:

(A) The following direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers are removed:

(1) Names;

(2) Postal address information, other than town or city, State and zip code;

(3) Telephone numbers;

(4) Fax numbers;

(5) Electronic mail addresses;

(6) Social security numbers or taxpayer identification numbers;

(7) Provider or practitioner credentialing or DEA numbers;

(8) National provider identification number;

(9) Certificate/license numbers;

(10) Web Universal Resource Locators (URLs);

(11) Internet Protocol (IP) address numbers;

(12) Biometric identifiers, including finger and voice prints; and

(13) Full face photographic images and any comparable images; and

(B) With respect to any individually identifiable health information in such patient safety work product, the direct identifiers listed at 45 CFR 164.514(e)(2) have been removed.

(5) *Disclosure of nonidentifiable patient safety work product.* Disclosure of non-identifiable patient safety work product when patient safety work product meets the standard for nonidentification in accordance with § 3.212 of this subpart.

(6) *Disclosure for research.* (i) Disclosure of patient safety work product to persons carrying out research, evaluation or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research.

(ii) If the patient safety work product disclosed pursuant to paragraph (b)(6)(i) of this section is by a HIPAA covered entity as defined at 45 CFR 160.103 and contains protected health information as defined by the HIPAA Privacy Rule at 45 CFR 160.103, such patient safety work product may only be disclosed under this exception in the same manner as would be permitted under the HIPAA Privacy Rule.

(7) *Disclosure to the Food and Drug Administration (FDA) and entities required to report to FDA.* (i) Disclosure by a provider of patient safety work product concerning an FDA-regulated product or activity to the FDA, an entity required to report to the FDA concerning the quality, safety, or effectiveness of an FDA-regulated product or activity, or a contractor acting on behalf of FDA or such entity for these purposes.

(ii) Any person permitted to receive patient safety work product pursuant to paragraph (b)(7)(i) of this section may only further disclose such patient safety work product for the purpose of evaluating the quality, safety, or effectiveness of that product or activity to another such person or the disclosing provider.

(8) *Voluntary disclosure to an accrediting body.* (i) Voluntary disclosure by a provider of patient safety work product to an accrediting body that accredits that provider, provided, with respect to any identified provider other than the provider making the disclosure:

(A) The provider agrees to the disclosure; or

(B) The identifiers at § 3.206(b)(4)(iv)(A) are removed.

(ii) An accrediting body may not further disclose patient safety work prod-

uct it receives pursuant to paragraph (b)(8)(i) of this section.

(iii) An accrediting body may not take an accrediting action against a provider based on a good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this Part. An accrediting body may not require a provider to reveal its communications with any PSO.

(9) *Disclosure for business operations.*

(i) Disclosure of patient safety work product by a provider or a PSO for business operations to attorneys, accountants, and other professionals. Such contractors may not further disclose patient safety work product, except to the entity from which they received the information.

(ii) Disclosure of patient safety work product for such other business operations that the Secretary may prescribe by regulation as consistent with the goals of this part.

(10) *Disclosure to law enforcement.* (i) Disclosure of patient safety work product to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime, provided that the disclosing person believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(ii) Law enforcement personnel receiving patient safety work product pursuant to paragraph (b)(10)(i) of this section only may disclose that patient safety work product to other law enforcement authorities as needed for law enforcement activities related to the event that gave rise to the disclosure under paragraph (b)(10)(i) of this section.

(c) *Safe harbor.* A provider or responsible person, but not a PSO, is not considered to have violated the requirements of this subpart if a member of its workforce discloses patient safety work product, provided that the disclosure does not include materials, including oral statements, that:

(1) Assess the quality of care of an identifiable provider; or

(2) Describe or pertain to one or more actions or failures to act by an identifiable provider.

(d) *Implementation and enforcement by the Secretary.* The confidentiality provisions shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

(e) *No limitation on authority to limit or delegate disclosure or use.* Nothing in subpart C of this part shall be construed to limit the authority of any person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this subpart.

#### **§ 3.208 Continued protection of patient safety work product.**

(a) Except as provided in paragraph (b) of this section, patient safety work product disclosed in accordance with this subpart, or disclosed impermissibly, shall continue to be privileged and confidential.

(b)(1) Patient safety work product disclosed for use in a criminal proceeding pursuant to section 922(c)(1)(A) of the Public Health Service Act, 42 U.S.C. 299b-22(c)(1)(A), and/or pursuant to § 3.206(b)(1) of this subpart continues to be privileged, but is no longer confidential.

(2) Non-identifiable patient safety work product that is disclosed is no longer privileged or confidential and not subject to the regulations under this part.

(3) Paragraph (b) of this section applies only to the specific patient safety work product disclosed.

#### **§ 3.210 Required disclosure of patient safety work product to the Secretary.**

Notwithstanding any other provision in this part, providers, PSOs, and responsible persons must disclose patient safety work product upon request by the Secretary when the Secretary determines such patient safety work

product is needed to investigate or determine compliance or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

#### **§ 3.212 Nonidentification of patient safety work product.**

(a) Patient safety work product is nonidentifiable with respect to a particular identified provider or a particular identified reporter if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an identified provider or reporter; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of such provider or reporter and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers or reporters are removed:

(A) The direct identifiers listed at § 3.206(b)(4)(iv)(A)(1) through (13) of this subpart;

(B) Geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people;

(C) All elements of dates (except year) for dates directly related to a patient safety incident or event; and

(D) Any other unique identifying number, characteristic, or code except as permitted for re-identification; and

(ii) The provider, PSO or responsible person making the disclosure does not

have actual knowledge that the information could be used, alone or in combination with other information that is reasonably available to the intended recipient, to identify the particular provider or reporter.

(3) *Re-identification.* A provider, PSO, or responsible person may assign a code or other means of record identification to allow information made nonidentifiable under this section to be re-identified by such provider, PSO, or responsible person, provided that:

(i) The code or other means of record identification is not derived from or related to information about the provider or reporter and is not otherwise capable of being translated so as to identify the provider or reporter; and

(ii) The provider, PSO, or responsible person does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(b) Patient safety work product is non-identifiable with respect to a particular patient only if the individually identifiable health information regarding that patient is de-identified in accordance with the HIPAA Privacy Rule standard and implementation specifications for the de-identification at 45 CFR 164.514(a) through (c).

## Subpart D—Enforcement Program

### § 3.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable, seek the cooperation of providers, PSOs, and responsible persons in obtaining compliance with the applicable confidentiality provisions.

(b) *Assistance.* The Secretary may provide technical assistance to providers, PSOs, and responsible persons to help them comply voluntarily with the applicable confidentiality provisions.

### § 3.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes that patient safety work product has been disclosed in violation of the confidentiality provisions may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the person that is the subject of the complaint and describe the act(s) believed to be in violation of the applicable confidentiality provision(s).

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the FEDERAL REGISTER.

(c) *Investigation.* The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the respondent and of the circumstances regarding any alleged violation. At the time of initial written communication with the respondent about the complaint, the Secretary will describe the act(s) that are the basis of the complaint.

### § 3.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether a respondent is complying with the applicable confidentiality provisions.

### § 3.310 Responsibilities of respondents.

(a) *Provide records and compliance reports.* A respondent must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the respondent has complied or is complying with the applicable confidentiality provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A respondent must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the respondent to determine whether it is complying with the applicable confidentiality provisions.

(c) *Permit access to information.* (1) A respondent must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including patient safety work product, that are pertinent to ascertaining compliance with the applicable confidentiality provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a respondent must permit access by the Secretary at any time and without notice.

(2) If any information required of a respondent under this section is in the exclusive possession of any other agency, institution, or person, and the other agency, institution, or person fails or refuses to furnish the information, the respondent must so certify and set forth what efforts it has made to obtain the information.

#### **§ 3.312 Secretarial action regarding complaints and compliance reviews.**

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to § 3.306 of this subpart or a compliance review pursuant to § 3.308 of this subpart indicates noncompliance, the Secretary may attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the respondent and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the respondent and provide the respondent an opportunity to submit written evidence of any mitigating factors. The respondent must submit any evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 3.526 of this subpart) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary decides that a civil money penalty should be imposed, inform the

respondent of such finding in a notice of proposed determination in accordance with § 3.420 of this subpart.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to § 3.306 of this subpart or a compliance review pursuant to § 3.308 of this subpart, the Secretary determines that further action is not warranted, the Secretary will so inform the respondent and, if the matter arose from a complaint, the complainant, in writing.

(c) *Uses and disclosures of information obtained.* (1) Identifiable patient safety work product obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except in accordance with § 3.206(d) of this subpart, or if otherwise permitted by this part or the Patient Safety Act.

(2) Except as provided for in paragraph (c)(1) of this section, information, including testimony and other evidence, obtained by the Secretary in connection with an investigation or compliance review under this subpart may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.

#### **§ 3.314 Investigational subpoenas and inquiries.**

(a) The Secretary may issue subpoenas in accordance with 42 U.S.C. 405(d) and (e), and 1320a-7a(j), to require the attendance and testimony of witnesses and the production of any other evidence including patient safety work product during an investigation or compliance review pursuant to this part.

(1) A subpoena issued under this paragraph must—

(i) State the name of the person (including the entity, if applicable) to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any documents or items required to be produced; and

(v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the entity must designate one or more natural persons who will testify on its behalf, and must state as to each such person that person's name and address and the matters on which he or she will testify. The designated person must testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by—

(i) Delivering a copy to the natural person named in the subpoena or to the entity named in the subpoena at its last principal place of business; or

(ii) Registered or certified mail addressed to the natural person at his or her last known dwelling place or to the entity at its last known principal place of business.

(3) A verified return by the natural person serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, constitutes proof of service.

(4) Witnesses are entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Fees need not be paid at the time the subpoena is served.

(5) A subpoena under this section is enforceable through the district court of the United States for the district where the subpoenaed natural person resides or is found or where the entity transacts business.

(b) Investigational inquiries are non-public investigational proceedings conducted by the Secretary.

(1) Testimony at investigational inquiries will be taken under oath or affirmation.

(2) Attendance of non-witnesses is discretionary with the Secretary, except that a witness is entitled to be accompanied, represented, and advised by an attorney.

(3) Representatives of the Secretary are entitled to attend and ask questions.

(4) A witness will have the opportunity to clarify his or her answers on

the record following questioning by the Secretary.

(5) Any claim of privilege must be asserted by the witness on the record.

(6) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to objection.

(7) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the Secretary may seek enforcement of the subpoena under paragraph (a)(5) of this section.

(8) The proceedings will be recorded and transcribed. The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(9)(i) The transcript will be submitted to the witness for signature.

(A) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the Secretary written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days (computed in the same manner as prescribed under § 3.526 of this part) of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(B) Where, as provided in paragraph (b)(8) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days (computed in the same manner as prescribed

under §3.526 of this part) of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(ii) The Secretary's proposed corrections to the record of transcript will be attached to the transcript.

#### **§ 3.402 Basis for a civil money penalty.**

(a) *General rule.* A person who discloses identifiable patient safety work product in knowing or reckless violation of the confidentiality provisions shall be subject to a civil money penalty for each act constituting such violation.

(b) *Violation attributed to a principal.* A principal is independently liable, in accordance with the federal common law of agency, for a civil money penalty based on the act of the principal's agent, including a workforce member, acting within the scope of the agency if such act could give rise to a civil money penalty in accordance with §3.402(a) of this subpart.

#### **§ 3.404 Amount of a civil money penalty.**

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and §3.408 of this subpart.

(b) The Secretary may impose a civil money penalty in the amount of not more than \$10,000.

EFFECTIVE DATE NOTE: At 74 FR 42779, Aug. 25, 2009, §3.404 was amended by revising paragraph (b), effective November 23, 2009. For the convenience of the user, the revised text is set forth as follows:

#### **§ 3.404 Amount of a civil money penalty.**

\* \* \* \* \*

(b) The Secretary may impose a civil money penalty in the amount of not more than \$11,000.

#### **§ 3.408 Factors considered in determining the amount of a civil money penalty.**

In determining the amount of any civil money penalty, the Secretary may consider as aggravating or mitigating factors, as appropriate, any of the following:

(a) The nature of the violation.

(b) The circumstances, including the consequences, of the violation, including:

(1) The time period during which the violation(s) occurred; and

(2) Whether the violation caused physical or financial harm or reputational damage;

(c) The degree of culpability of the respondent, including:

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the respondent.

(d) Any history of prior compliance with the Patient Safety Act, including violations, by the respondent, including:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the respondent has attempted to correct previous violations;

(3) How the respondent has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the respondent has responded to prior complaints.

(e) The financial condition of the respondent, including:

(1) Whether the respondent had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the respondent to continue to provide health care or patient safety activities; and

(3) The size of the respondent.

(f) Such other matters as justice may require.

#### **§ 3.414 Limitations.**

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with §3.420 of this subpart, within 6 years from the date of the occurrence of the violation.

#### **§ 3.416 Authority to settle.**

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

## **§ 3.418**

### **§ 3.418 Exclusivity of penalty.**

(a) Except as otherwise provided by paragraph (b) of this section, a penalty imposed under this part is in addition to any other penalty prescribed by law.

(b) Civil money penalties shall not be imposed both under this part and under the HIPAA Privacy Rule (45 CFR parts 160 and 164).

### **§ 3.420 Notice of proposed determination.**

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent, written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include:

(1) Reference to the statutory basis for the penalty;

(2) A description of the findings of fact regarding the violations with respect to which the penalty is proposed;

(3) The reason(s) why the violation(s) subject(s) the respondent to a penalty;

(4) The amount of the proposed penalty;

(5) Any factors described in § 3.408 of this subpart that were considered in determining the amount of the proposed penalty; and

(6) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty without the right to a hearing under § 3.504 of this subpart or a right of appeal under § 3.548 of this subpart, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed penalty by filing a request in accordance with § 3.504 of this subpart.

### **§ 3.422 Failure to request a hearing.**

If the respondent does not request a hearing within the time prescribed by § 3.504 of this subpart and the matter is not settled pursuant to § 3.416 of this subpart, the Secretary may impose the proposed penalty or any lesser penalty permitted by sections 921 through 926 of the Public Health Service Act, 42 U.S.C. 299b-21 through 299b-26. The Sec-

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retary will notify the respondent by certified mail, return receipt requested, of any penalty that has been imposed and of the means by which the respondent may satisfy the penalty, and the penalty is final on receipt of the notice. The respondent has no right to appeal a penalty under § 3.548 of this subpart with respect to which the respondent has not timely requested a hearing.

### **§ 3.424 Collection of penalty.**

(a) Once a determination of the Secretary to impose a penalty has become final, the penalty will be collected by the Secretary, subject to the first sentence of 42 U.S.C. 1320a-7a(f).

(b) The penalty may be recovered in a civil action brought in the United States district court for the district where the respondent resides, is found, or is located.

(c) The amount of a penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ, or in an appeal under 42 U.S.C. 1320a-7a(e), may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

### **§ 3.426 Notification of the public and other agencies.**

Whenever a proposed penalty becomes final, the Secretary will notify, in such manner as the Secretary deems appropriate, the public and the following organizations and entities thereof and the reason it was imposed: The appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in 42 U.S.C. 1320a-7(h)), the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in 42 U.S.C. 1395aa(a), 1396a(a)(33)).



**§ 3.504 Hearings before an ALJ.**

(a) A respondent may request a hearing before an ALJ. The parties to the hearing proceeding consist of—

- (1) The respondent; and
- (2) The officer(s) or employee(s) of HHS to whom the enforcement authority involved has been delegated.

(b) The request for a hearing must be made in writing signed by the respondent or by the respondent's attorney and sent by certified mail, return receipt requested, to the address specified in the notice of proposed determination. The request for a hearing must be mailed within 60 days after notice of the proposed determination is received by the respondent. For purposes of this section, the respondent's date of receipt of the notice of proposed determination is presumed to be 5 days after the date of the notice unless the respondent makes a reasonable showing to the contrary to the ALJ.

(c) The request for a hearing must clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the respondent has any knowledge. If the respondent has no knowledge of a particular finding of fact and so states, the finding shall be deemed denied. The request for a hearing must also state the circumstances or arguments that the respondent alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty.

(d) The ALJ must dismiss a hearing request where—

- (1) On motion of the Secretary, the ALJ determines that the respondent's hearing request is not timely filed as required by paragraph (b) or does not meet the requirements of paragraph (c) of this section;
- (2) The respondent withdraws the request for a hearing;
- (3) The respondent abandons the request for a hearing; or
- (4) The respondent's hearing request fails to raise any issue that may properly be addressed in a hearing.

**§ 3.506 Rights of the parties.**

(a) Except as otherwise limited by this subpart, each party may—

(1) Be accompanied, represented, and advised by an attorney;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery of documents as permitted by this subpart;

(4) Agree to stipulations of fact or law that will be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) A party may appear in person or by a representative. Natural persons who appear as an attorney or other representative must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.

(c) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of 42 U.S.C. 406, which authorizes the Secretary to specify or limit their fees.

**§ 3.508 Authority of the ALJ.**

(a) The ALJ must conduct a fair and impartial hearing, avoid delay, maintain order, and ensure that a record of the proceeding is made.

(b) The ALJ may—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of documentary discovery as permitted by this subpart;

### § 3.510

(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone; and

(13) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact. A summary judgment decision constitutes a hearing on the record for the purposes of this subpart.

(c) The ALJ—

(1) May not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must give deference to published guidance to the extent not inconsistent with statute or regulation;

(2) May not enter an order in the nature of a directed verdict;

(3) May not compel settlement negotiations; or

(4) May not enjoin any act of the Secretary.

### § 3.510 Ex parte contacts.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

### § 3.512 Prehearing conferences.

(a) The ALJ must schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice, which may not be less than 14 business days, to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

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(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this subpart;

(9) The time and place for the hearing;

(10) The potential for the settlement of the case by the parties; and

(11) Other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings, including the protection of confidentiality of identifiable patient safety work product that may be submitted into evidence or otherwise used in the proceeding, if appropriate.

(c) The ALJ must issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

### § 3.514 Authority to settle.

The Secretary has exclusive authority to settle any issue or case without the consent of the ALJ.

### § 3.516 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying that are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term “documents” includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories,

depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section may not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request must either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part must be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. The party receiving a request for production may also file a motion for protective order any time before the date the production is due.

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

- (i) Is irrelevant;
- (ii) Is unduly costly or burdensome;
- (iii) Will unduly delay the proceeding; or
- (iv) Seeks privileged information.

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

**§ 3.518 Exchange of witness lists, witness statements, and exhibits.**

(a) The parties must exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 3.538, not more than 60, and not less than 15, days before the scheduled hearing.

(b)(1) If, at any time, a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ must determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of that evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure timely to exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief—

(i) The testimony of any witness whose name does not appear on the witness list; and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of that evidence would cause substantial prejudice to the objecting party.

(i) If the ALJ finds that there is no substantial prejudice, the evidence may be admitted.

(ii) If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or, if he or she does not exclude the evidence, must postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence, unless the objecting party waives postponement.

(c) Unless the other party objects within a reasonable period of time before the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

**§ 3.520 Subpoenas for attendance at hearing.**

(a) A party wishing to procure the appearance and testimony of any person at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of a person in accordance with paragraph (a) of this section may also require the person (whether or not the

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person is a party) to produce relevant and material evidence at or before the hearing.

(c) When a subpoena is served by a respondent on a particular employee or official or particular office of HHS, the Secretary may comply by designating any knowledgeable HHS representative to appear and testify.

(d) A party seeking a subpoena must file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. That motion must—

(1) Specify any evidence to be produced;

(2) Designate the witnesses; and

(3) Describe the address and location with sufficient particularity to permit those witnesses to be found.

(e) The subpoena must specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena must serve it by delivery to the person named, or by certified mail addressed to that person at the person's last dwelling place or principal place of business.

(h) The person to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in 42 U.S.C. 405(e).

### § 3.522 Fees.

The party requesting a subpoena must pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage must accompany the subpoena when served, except that, when a subpoena is issued on behalf of the Secretary, a check for witness fees and mileage need not accompany the subpoena.

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### § 3.524 Form, filing, and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ must include an original and two copies.

(2) Every pleading and paper filed in the proceeding must contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper must be signed by and must contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Board must, at the time of filing, serve a copy of the document on the other party. Service upon any party of any document must be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service must be made upon the attorney in lieu of the party.

(c) *Proof of service.* A certificate of the natural person serving the document by personal delivery or by mail, setting forth the manner of service, constitutes proof of service.

### § 3.526 Computation of time.

(a) In computing any period of time under this subpart or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government must be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This

paragraph does not apply to requests for hearing under § 3.504.

#### § 3.528 Motions.

(a) An application to the ALJ for an order or ruling must be by motion. Motions must state the relief sought, the authority relied upon and the facts alleged, and must be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions must be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to the motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny the motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all outstanding motions before the beginning of the hearing.

#### § 3.530 Sanctions.

The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. The sanctions must reasonably relate to the severity and nature of the failure or misconduct. The sanctions may include—

(a) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating the refusal as an admission by deeming the matter, or certain facts, to be established;

(b) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(c) Striking pleadings, in whole or in part;

(d) Staying the proceedings;

(e) Dismissal of the action;

(f) Entering a decision by default;

(g) Ordering the party or attorney to pay the attorney's fees and other costs

caused by the failure or misconduct; and

(h) Refusing to consider any motion or other action that is not filed in a timely manner.

#### § 3.532 Collateral estoppel.

When a final determination that the respondent violated a confidentiality provision has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

#### § 3.534 The hearing.

(a) The ALJ must conduct a hearing on the record in order to determine whether the respondent should be found liable under this part.

(b)(1) The respondent has the burden of going forward and the burden of persuasion with respect to any challenge to the amount of a proposed penalty pursuant to §§ 3.404 and 3.408, including any factors raised as mitigating factors.

(2) The Secretary has the burden of going forward and the burden of persuasion with respect to all other issues, including issues of liability and the existence of any factors considered as aggravating factors in determining the amount of the proposed penalty.

(3) The burden of persuasion will be judged by a preponderance of the evidence.

(c) The hearing must be open to the public unless otherwise ordered by the ALJ for good cause shown, which may be that identifiable patient safety work product has been introduced into evidence or is expected to be introduced into evidence.

(d)(1) Subject to the 15-day rule under § 3.518(a) and the admissibility of evidence under § 3.540, either party may introduce, during its case in chief, items or information that arose or became known after the date of the issuance of the notice of proposed determination or the request for hearing, as applicable. Such items and information may not be admitted into evidence, if introduced—

(i) By the Secretary, unless they are material and relevant to the acts or omissions with respect to which the

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penalty is proposed in the notice of proposed determination pursuant to § 3.420 of this part, including circumstances that may increase penalties; or

(ii) By the respondent, unless they are material and relevant to an admission, denial or explanation of a finding of fact in the notice of proposed determination under § 3.420 of this part, or to a specific circumstance or argument expressly stated in the request for hearing under § 3.504, including circumstances that may reduce penalties.

(2) After both parties have presented their cases, evidence may be admitted in rebuttal even if not previously exchanged in accordance with § 3.518.

#### § 3.538 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing must be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony of witnesses other than the testimony of expert witnesses may be admitted in the form of a written statement. The ALJ may, at his or her discretion, admit prior sworn testimony of experts that has been subject to adverse examination, such as a deposition or trial testimony. Any such written statement must be provided to the other party, along with the last known address of the witness, in a manner that allows sufficient time for the other party to subpoena the witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing must be exchanged as provided in § 3.518.

(c) The ALJ must exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth;

(2) Avoid repetition or needless consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ must permit the parties to conduct cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the

testimony of other witnesses, except that the ALJ may not order to be excluded—

(1) A party who is a natural person;

(2) In the case of a party that is not a natural person, the officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

(3) A natural person whose presence is shown by a party to be essential to the presentation of its case, including a person engaged in assisting the attorney for the Secretary.

#### § 3.540 Evidence.

(a) The ALJ must determine the admissibility of evidence.

(b) Except as provided in this subpart, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement is inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs, or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. This evidence is admissible regardless of whether the crimes, wrongs, or acts occurred during the statute of limitations period applicable to the acts or omissions that constitute the basis for liability in the case and regardless of whether they were referenced in the Secretary's notice of proposed determination under § 3.420.

(h) The ALJ must permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.

**§ 3.542 The record.**

(a) The hearing must be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ. A party that requests a transcript of hearing proceedings must pay the cost of preparing the transcript unless, for good cause shown by the party, the payment is waived by the ALJ or the Board, as appropriate.

(b) The transcript of the testimony, exhibits, and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown, which may include the presence in the record of identifiable patient safety work product.

(d) For good cause, which may include the presence in the record of identifiable patient safety work product, the ALJ may order appropriate redactions made to the record.

**§ 3.544 Post hearing briefs.**

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ must fix the time for filing the briefs. The time for filing may not exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. The briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

**§ 3.546 ALJ's decision.**

(a) The ALJ must issue a decision, based only on the record, which must contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase, or reduce the penalties imposed by the Secretary.

(c) The ALJ must issue the decision to both parties within 60 days after the

time for submission of post-hearing briefs and reply briefs, if permitted, has expired. If the ALJ fails to meet the deadline contained in this paragraph, he or she must notify the parties of the reason for the delay and set a new deadline.

(d) Unless the decision of the ALJ is timely appealed as provided for in § 3.548, the decision of the ALJ will be final and binding on the parties 60 days from the date of service of the ALJ's decision.

**§ 3.548 Appeal of the ALJ's decision.**

(a) Any party may appeal the decision of the ALJ to the Board by filing a notice of appeal with the Board within 30 days of the date of service of the ALJ decision. The Board may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the Board a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the Board, the ALJ must forward the record of the proceeding to the Board.

(c) A notice of appeal must be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to the exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and the accompanying brief. The Board may permit the parties to file reply briefs.

(d) There is no right to appear personally before the Board or to appeal to the Board any interlocutory ruling by the ALJ.

(e) The Board may not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the Board that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the Board may remand the matter to the ALJ for consideration of such additional evidence.

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(g) The Board may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision of the ALJ is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the Board must serve on each party to the appeal a copy of the Board's decision and a statement describing the right of any respondent who is penalized to seek judicial review.

(j)(1) The Board's decision under paragraph (i) of this section, including a decision to decline review of the initial decision, becomes the final decision of the Secretary 60 days after the date of service of the Board's decision, except with respect to a decision to remand to the ALJ or if reconsideration is requested under this paragraph.

(2) The Board will reconsider its decision only if it determines that the decision contains a clear error of fact or error of law. New evidence will not be a basis for reconsideration unless the party demonstrates that the evidence is newly discovered and was not previously available.

(3) A party may file a motion for reconsideration with the Board before the date the decision becomes final under paragraph (j)(1) of this section. A motion for reconsideration must be accompanied by a written brief specifying any alleged error of fact or law and, if the party is relying on additional evidence, explaining why the evidence was not previously available. Any party may file a brief in opposition within 15 days of receiving the motion for reconsideration and the accompanying brief unless this time limit is extended by the Board for good cause shown. Reply briefs are not permitted.

(4) The Board must rule on the motion for reconsideration not later than 30 days from the date the opposition brief is due. If the Board denies the motion, the decision issued under paragraph (i) of this section becomes the final decision of the Secretary on the

date of service of the ruling. If the Board grants the motion, the Board will issue a reconsidered decision, after such procedures as the Board determines necessary to address the effect of any error. The Board's decision on reconsideration becomes the final decision of the Secretary on the date of service of the decision, except with respect to a decision to remand to the ALJ.

(5) If service of a ruling or decision issued under this section is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k)(1) A respondent's petition for judicial review must be filed within 60 days of the date on which the decision of the Board becomes the final decision of the Secretary under paragraph (j) of this section.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging the final decision of the Secretary must be sent by certified mail, return receipt requested, to the General Counsel of HHS. The petition copy must be a copy showing that it has been time-stamped by the clerk of the court when the original was filed with the court.

(3) If the General Counsel of HHS received two or more petitions within 10 days after the final decision of the Secretary, the General Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10 day period.

#### § 3.550 Stay of the Secretary's decision.

(a) Pending judicial review, the respondent may file a request for stay of the effective date of any penalty with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of the request automatically stays the effective date of the penalty until such time as the ALJ rules upon the request.

(b) The ALJ may not grant a respondent's request for stay of any penalty unless the respondent posts a bond or provides other adequate security.

(c) The ALJ must rule upon a respondent's request for stay within 10 days of receipt.



**§ 3.552 Harmless error.**

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the Board inconsistent with substantial justice. The ALJ and the Board at every stage of the proceeding must disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

## PART 4—NATIONAL LIBRARY OF MEDICINE

Sec.

- 4.1 Programs to which these regulations apply.
- 4.2 Definitions.
- 4.3 Purpose of the Library.
- 4.4 Use of Library facilities.
- 4.5 Use of materials from the collections.
- 4.6 Reference, bibliographic, reproduction, and consultation services.
- 4.7 Fees.
- 4.8 Publication of the Library and information about the Library.

AUTHORITY: 42 U.S.C. 216, 286.

SOURCE: 56 FR 29188, June 26, 1991, unless otherwise noted.

**§ 4.1 Programs to which these regulations apply.**

(a) The regulations of this part govern access to the National Library of Medicine's facilities and library collections and the availability of its bibliographic, reproduction, reference, and related services. These functions are performed by the Library directly for the benefit of the general public and health-sciences professionals as required by sections 465(b) (3)–(6) of the Act (42 U.S.C. 286(b) (3)–(6)).

(b) The regulations of this part do not apply to:

(1) The Library's internal functions relating to the acquisition and preservation of materials and the organization of these materials as required by sections 465(b) (1) and (2) of the Act (42 U.S.C. 286(b) (1) and (2)).

(2) The availability of "records" under the Freedom of Information Act

or the Privacy Act of 1974 (5 U.S.C. 552, 552a). These matters are covered in 45 CFR parts 5 and 5b.

(3) Federal assistance for medical libraries and other purposes which are authorized by sections 469–477 of the Act (42 U.S.C. 286b to 286b–8). (See parts 59a, 61 and 64 of this chapter.)

(4) The availability of facilities, collections, and related services of Regional Medical Libraries established or maintained under the authority in section 475 of the Act (42 U.S.C. 286b–6). (See part 59a, subpart B of this chapter.)

**§ 4.2 Definitions.**

As used in this part:

*Act* means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

*Collections* means all books, periodicals, prints, audiovisual materials, films, videotapes, recordings, manuscripts, and other resource materials of the library. It does not include data processing tapes or programs used solely for internal processing activities to generate reference materials, nor does it include "records" of the Library as defined in 45 CFR 5.5. Records of the Library are available in accordance with the regulations under the Freedom of Information Act and Privacy Act of 1974. (See 45 CFR parts 5 and 5b.)

*Director* means the Director of the National Library of Medicine or the Director's delegate.

*Health-sciences professional* means any person engaged in: (1) The administration of health activities; (2) the provision of health services; or (3) research, teaching, or education concerned with the advancement of medicine or other sciences related to health or improvement of the public health.

*Historical collection* means: (1) Materials in the collections published or printed prior to 1914; (2) manuscripts and prints; (3) the archival film collection; and (4) other materials of the collections which, because of age, or unique or unusual value, require special handling, storage, or protection for their preservation, as determined by the Director.

*Library* means the National Library of Medicine, established by section 465 of the Act (42 U.S.C. 286).

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*Regional Medical Library* means a medical library established or maintained as a regional medical library under section 475 of the Act (42 U.S.C. 286b-6).

### § 4.3 Purpose of the Library.

The purpose of the Library is to assist the advancement of medical and related sciences and aid the dissemination and exchange of scientific and other information important to the progress of medicine and the public health. The Library acquires and maintains library materials pertinent to medicine, including audiovisual materials; compiles, publishes, and disseminates catalogs, indices, and bibliographies of these materials, as appropriate; makes available materials, through loan or otherwise; provides reference and other assistance to research; and engages in other activities in furtherance of this purpose.

### § 4.4 Use of Library facilities.

(a) *General.* The Library facilities are available to any person seeking to make use of the collections. The Director may prescribe reasonable rules to assure the most effective use of facilities by health-sciences professionals and to protect the collections from misuse or damage. These rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination.

(b) *Reading rooms.* Public reading rooms are available for obtaining and reading materials from the collections. The Director may prescribe reasonable rules designed to provide adequate reading space and orderly conditions and procedures.

(c) *Study rooms.* Upon request a limited number of study rooms may be made available to individuals requiring extensive use of Library materials. Requests for study rooms shall be addressed in writing to the Director. The Director shall give priority, in the following order, for study room use to:

(1) Persons engaged in "special scientific projects" under section 473 of the Act (42 U.S.C. 286b-4),

(2) Health-sciences professionals, and

(3) The general public.

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### § 4.5 Use of materials from the collections.

(a) *Unrestricted materials.* Except as otherwise provided in this section, materials from the collections are generally available to any interested person only in facilities provided by the Library for this purpose. The Director may prescribe additional reasonable rules to assure the most effective use of the Library's resources by health-sciences professionals and to protect the collections from misuse or damage. The rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination. Materials in the collections are available upon each request which assures, to the Director's satisfaction, that the materials will be safeguarded from misuse, damage, loss, or misappropriation, and will be returned promptly after use or upon request of the Library.

(b) *Restricted materials*—(1) *Historical collection.* Materials from the historical collection are available only as the Director may permit to assure their maximum preservation and protection. Copies of these materials may be made available in the form of microfilm and other copies, for which reasonable fees may be charged.

(2) *Gifts.* Materials in the collections are available only in accordance with any limitations imposed as a condition of the acquisition of those materials, whether the acquisition was by gift or purchase.

(c) *Loans*—(1) *General.* Requests for loans of materials must assure the Library that (i) the materials will be safeguarded from misuse, damage, loss, or misappropriation and (ii) the materials will be returned promptly after use or upon request of the Library. The Library may provide copies in lieu of original materials, which need not be returned unless otherwise stated at the time of the loan.

(2) *Loans of audiovisual materials.* Audiovisual materials are available for loan under the same general terms as printed materials.

(3) *Loans to other libraries.* Upon request materials or copies are available for use through libraries of public or private agencies or institutions. The requesting library must assure that it

has first exhausted its own collection resources, those of other local libraries in the geographic area, and those of the Regional Medical Library network (including Regional and Resource Libraries) before making a request for a loan.

(4) *Loans to health-sciences professionals.* The Director may make loans of materials directly to health-sciences professionals. An individual wishing a loan of library materials must assure to the satisfaction of the Director that the individual is geographically isolated, in terms of distance or available transportation, from medical literature resources likely to contain the desired material.

(Approved by the Office of Management and Budget under control number 0925-0276)

**§ 4.6 Reference, bibliographic, reproduction, and consultation services.**

(a) *General.* To the extent resources permit, the Library will make available, upon request, reference, bibliographic, reproduction, and consultation services. Priority will be given to requests from health-sciences professionals for services not reasonably available through local or regional libraries.

(b) *Specialized bibliographic services.* The Director may provide bibliographies on individually selected medical or scientific topics upon request where it is consistent with the Library's purpose. The Director may publish and make available for general distribution by the Library, bibliographic searches determined to be of general interest. The Library may also produce and distribute a limited number of bibliographies on topics of general interest to public or nonprofit health-related professional societies, research organizations, and other group users. These bibliographies may be produced on a regularly recurring or intermittent basis under contract between the Library and public or nonprofit agencies, when determined in each case by the Director to be necessary to assure more effective distribution of the bibliographic information.

(c) *Information retrieval system computer tapes.* To the extent Library resources permit and in order to further the Library's purpose, the Director may make available upon request by

agencies, organizations, and institutions copies of all or part of the Library's magnetic tapes.

**§ 4.7 Fees.**

The Director may charge reasonable fees for any service provided by the Library under this part, in accordance with a schedule available at the Library upon request, which are designed to recover all or a portion of the cost to the Library of providing the service.

**§ 4.8 Publication of the Library and information about the Library.**

Lists of bibliographies, Library publications sold by the Government Printing Office, necessary application forms, and other information concerning the organization, operation, functions, and services of the Library, are available from the National Library of Medicine, Bethesda, Maryland 20894.

**PART 5—DESIGNATION OF HEALTH PROFESSIONAL(S) SHORTAGE AREAS**

Sec.

5.1 Purpose.

5.2 Definitions.

5.3 Procedures for designation of health professional(s) shortage areas.

5.4 Notification and publication of designations and withdrawals.

APPENDIX A TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PRIMARY MEDICAL CARE PROFESSIONAL(S)

APPENDIX B TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF DENTAL PROFESSIONAL(S)

APPENDIX C TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF MENTAL HEALTH PROFESSIONALS

APPENDIX D TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VISION CARE PROFESSIONAL(S)

APPENDIX E TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PODIATRIC PROFESSIONAL(S)

APPENDIX F TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PHARMACY PROFESSIONAL(S)

APPENDIX G TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VETERINARY PROFESSIONAL(S)

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sec. 332 of the Public Health Service Act, 90 Stat. 2270-2272 (42 U.S.C. 254e).

## § 5.1

SOURCE: 45 FR 76000, Nov. 17, 1980, unless otherwise noted.

### § 5.1 Purpose.

These regulations establish criteria and procedures for the designation of geographic areas, population groups, medical facilities, and other public facilities, in the States, as health professional(s) shortage areas.

### § 5.2 Definitions.

*Act* means the Public Health Service Act, as amended.

*Health professional(s) shortage area* means any of the following which the Secretary determines has a shortage of health professional(s): (1) An urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services); (2) a population group; or (3) a public or nonprofit private medical facility.

*Health service area* means a health service area whose boundaries have been designated by the Secretary, under section 1511 of the Act, for purposes of health planning activities.

*Health systems agency* or *HSA* means the health systems agency designated, under section 1515 of the Act, to carry out health planning activities for a specific health service area.

*Medical facility* means a facility for the delivery of health services and includes: (1) A community health center, public health center, outpatient medical facility, or community mental health center; (2) a hospital, State mental hospital, facility for long-term care, or rehabilitation facility; (3) a migrant health center or an Indian Health service facility; (4) a facility for delivery of health services to inmates in a U.S. penal or correctional institution (under section 323 of the Act) or a State correctional institution; (5) a Public Health Service medical facility (used in connection with the delivery of health services under section 320, 321, 322, 324, 325, or 326 of the Act); or (6) any other Federal medical facility.

*Metropolitan area* means an area which has been designated by the Office of Management and Budget as a standard metropolitan statistical area

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(SMSA). All other areas are “non-metropolitan areas.”

*Poverty level* means the poverty level as defined by the Bureau of the Census, using the poverty index adopted by a Federal Interagency Committee in 1969, and updated each year to reflect changes in the Consumer Price Index.

*Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

*State* includes, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

*State health planning and development agency* or *SHPDA* means a State health planning and development agency designated under section 1521 of the Act.

### § 5.3 Procedures for designation of health professional(s) shortage areas.

(a) Using data available to the Department from national, State, and local sources and based upon the criteria in the appendices to this part, the Department will annually prepare listings (by State and health service area) of currently designated health professional(s) shortage areas and potentially designatable areas, together with appropriate related data available to the Department. Relevant portions of this material will then be forwarded to each health systems agency, State health planning and development agency, and Governor, who will be asked to review the listings for their State, correct any errors of which they are aware, and offer their recommendations, if any, within 90 days, as to which geographic areas, population groups, and facilities in areas under their jurisdiction should be designated. An information copy of these listings will also be made available, upon request, to interested parties for their use in providing comments or recommendations to the Secretary and/or to the appropriate HSA, SHPDA, or Governor.

(b) In addition, any agency or individual may request the Secretary to designate (or withdraw the designation

of) a particular geographic area, population group, or facility as a health professional(s) shortage area. Each request will be forwarded by the Secretary to the appropriate HSA, SHPDA, and Governor, who will be asked to review it and offer their recommendations, if any, within 30 days. An information copy will also be made available to other interested parties, upon request, for their use in providing comments or recommendations to the Secretary and/or to the appropriate HSA, SHPDA, or Governor.

(c) In each case where the designation of a public facility (including a Federal medical facility) is under consideration, the Secretary will give written notice of the proposed designation to the chief administrative officer of the facility, who will be asked to review it and offer their recommendations, if any, within 30 days.

(d) After review of the available information and consideration of the comments and recommendations submitted, the Secretary will designate health professional(s) shortage areas and withdraw the designation of any areas which have been determined no longer to have a shortage of health professional(s).

#### **§ 5.4 Notification and publication of designations and withdrawals.**

(a) The Secretary will give written notice of the designation (or withdrawal of designation) of a health professional(s) shortage area, not later than 60 days from the date of the designation (or withdrawal of designation), to:

(1) The Governor of each State in which the area, population group, medical facility, or other public facility so designated is in whole or in part located;

(2) Each HSA for a health service area which includes all or any part of the area, population group, medical facility, or other public facility so designated;

(3) The SHPDA for each State in which the area, population group, medical facility, or other public facility so designated is in whole or in part located; and

(4) Appropriate public or nonprofit private entities which are located in or

which have a demonstrated interest in the area so designated.

(b) The Secretary will periodically publish updated lists of designated health professional(s) shortage areas in the FEDERAL REGISTER, by type of professional(s) shortage. An updated list of areas for each type of professional(s) shortage will be published at least once annually.

(c) The effective date of the designation of an area shall be the date of the notification letter to the individual or agency which requested the designation, or the date of publication in the FEDERAL REGISTER, whichever comes first.

(d) Once an area is listed in the FEDERAL REGISTER as a designated health professional(s) shortage area, the effective date of any later withdrawal of the area's designation shall be the date when notification of the withdrawal, or an updated list of designated areas which does not include it, is published in the FEDERAL REGISTER.

#### **APPENDIX A TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PRIMARY MEDICAL CARE PROFESSIONAL(S)**

##### *Part I—Geographic Areas*

##### *A. Federal and State Correctional Institutions.*

###### *1. Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of primary medical care professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE primary care physicians serving the institution is at least 1,000:1.

Here the number of internees is defined as follows:

(i) If the number of new inmates per year and the average length-of-stay are not specified, or if the information provided does not indicate that intake medical examinations are routinely performed upon entry, then—  
Number of internees=average number of inmates.

(ii) If the average length-of-stay is specified as one year or more, and intake medical examinations are routinely performed upon entry, then—  
Number of internees=average number of inmates+(0.3)×number of new inmates per year.

(iii) If the average length-of-stay is specified as less than one year, and intake examinations are routinely performed upon entry, then—Number of internees=average number of inmates $\div$ (0.2) $\times$ (1+ALOS/2) $\times$ number of new inmates per year where ALOS=average length-of-stay (in fraction of year). (The number of FTE primary care physicians is computed as in part I, section B, paragraph 3 above.)

**2. Determination of Degree of Shortage.**

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to primary care physicians, as follows:

Group 1—Institutions with 500 or more inmates and no physicians.

Group 2—Other institutions with no physicians and institutions with R greater than (or equal to) 2,000:1.

Group 3—Institutions with R greater than (or equal to) 1,000:1 but less than 2,000:1.

**B. Methodology.**

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

**1. Rational Areas for the Delivery of Primary Medical Care Services.**

(a) The following areas will be considered rational areas for the delivery of primary medical care services:

(i) A county, or a group of contiguous counties whose population centers are within 30 minutes travel time of each other.

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns, distinctive population characteristics or other factors, has limited access to contiguous area resources, as measured generally by a travel time greater than 30 minutes to such resources.

(iii) Established neighborhoods and communities within metropolitan areas which display a strong self-identity (as indicated by a homogeneous socioeconomic or demographic structure and/or a tradition of interaction or interdependency), have limited interaction with contiguous areas, and which, in general, have a minimum population of 20,000.

(b) The following distances will be used as guidelines in determining distances corresponding to 30 minutes travel time:

(i) Under normal conditions with primary roads available: 20 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 15 miles.

(iii) In flat terrain or in areas connected by interstate highways: 25 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the

distance corresponding to 30 minutes travel time.

**2. Population Count.**

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions, with the following adjustments, where appropriate:

(a) Adjustments to the population for the differing health service requirements of various age-sex population groups will be computed using the table below of visit rates for 12 age-sex population cohorts. The total expected visit rate will first be obtained by multiplying each of the 12 visit rates in the table by the size of the area population within that particular age-sex cohort and adding the resultant 12 visit figures together. This total expected visit rate will then be divided by the U.S. average per capita visit rate of 5.1, to obtain the adjusted population for the area.

Sex	Age groups					
	Under 5	5–14	15–24	25–44	45–64	65 and over
Male .....	7.3	3.6	3.3	3.6	4.7	6.4
Female ..	6.4	3.2	5.5	6.4	6.5	6.8

(b) The effect of transient populations on the need of an area for primary care professional(s) will be taken into account as follows:

(i) Seasonal residents, i.e., those who maintain a residence in the area but inhabit it for only 2 to 8 months per year, may be included but must be weighted in proportion to the fraction of the year they are present in the area.

(ii) Other tourists (non-resident) may be included in an area's population but only with a weight of 0.25, using the following formula: Effective tourist contribution to population=0.25 $\times$ (fraction of year tourists are present in area) $\times$ (average daily number of tourists during portion of year that tourists are present).

(iii) Migratory workers and their families may be included in an area's population, using the following formula: Effective migrant contribution to population=(fraction of year migrants are present in area) $\times$ (average daily number of migrants during portion of year that migrants are present).

**3. Counting of Primary Care Practitioners.**

(a) All non-Federal doctors of medicine (M.D.) and doctors of osteopathy (D.O.) providing direct patient care who practice principally in one of the four primary care specialties—general or family practice, general internal medicine, pediatrics, and obstetrics

and gynecology—will be counted. Those physicians engaged solely in administration, research, and teaching will be excluded. Adjustments for the following factors will be made in computing the number of full-time-equivalent (FTE) primary care physicians:

(i) Interns and residents will be counted as 0.1 full-time equivalent (FTE) physicians.

(ii) Graduates of foreign medical schools who are not citizens or lawful permanent residents of the United States will be excluded from physician counts.

(iii) Those graduates of foreign medical schools who are citizens or lawful permanent residents of the United States, but do not have unrestricted licenses to practice medicine, will be counted as 0.5 FTE physicians.

(b) Practitioners who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who provide patient care services to the residents of the area only on a part-time basis will be discounted through the use of full-time equivalency figures. A 40-hour work week will be used as the standard for determining full-time equivalents in these cases. For practitioners working less than a 40-hour week, every four (4) hours (or  $\frac{1}{2}$  day) spent providing patient care, in either ambulatory or inpatient settings, will be counted as 0.1 FTE (with numbers obtained for FTE's rounded to the nearest 0.1 FTE), and each physician providing patient care 40 or more hours a week will be counted as 1.0 FTE physician. (For cases where data are available only for the number of hours providing patient care in office settings, equivalencies will be provided in guidelines.)

(c) In some cases, physicians located within an area may not be accessible to the population of the area under consideration. Allowances for physicians with restricted practices can be made, on a case-by-case basis. However, where only a portion of the population of the area cannot access existing primary care resources in the area, a population group designation may be more appropriate (see part II of this appendix).

(d) Hospital staff physicians involved exclusively in inpatient care will be excluded. The number of full-time equivalent physicians practicing in organized outpatient departments and primary care clinics will be included, but those in emergency rooms will be excluded.

(e) Physicians who are suspended under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act for a period of eighteen months or more will be excluded.

#### 4. *Determination of Unusually High Needs for Primary Medical Care Services.*

An area will be considered as having unusually high needs for primary health care services if at least one of the following criteria is met:

(a) The area has more than 100 births per year per 1,000 women aged 15-44.

(b) The area has more than 20 infant deaths per 1,000 live births.

(c) More than 20% of the population (or of all households) have incomes below the poverty level.

#### 5. *Determination of Insufficient Capacity of Existing Primary Care Providers.*

An area's existing primary care providers will be considered to have insufficient capacity if at least two of the following criteria are met:

(a) More than 8,000 office or outpatient visits per year per FTE primary care physician serving the area.

(b) Unusually long waits for appointments for routine medical services (*i.e.*, more than 7 days for established patients and 14 days for new patients).

(c) Excessive average waiting time at primary care providers (longer than one hour where patients have appointments or two hours where patients are treated on a first-come, first-served basis).

(d) Evidence of excessive use of emergency room facilities for routine primary care.

(e) A substantial proportion (2/3 or more) of the area's physicians do not accept new patients.

(f) Abnormally low utilization of health services, as indicated by an average of 2.0 or less office visits per year on the part of the area's population.

#### 6. *Contiguous Area Considerations.*

Primary care professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Primary care professional(s) in the contiguous area are more than 30 minutes travel time from the population center(s) of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The contiguous area population-to-full-time-equivalent primary care physician ratio is in excess of 2000:1, indicating that practitioners in the contiguous area cannot be expected to help alleviate the shortage situation in the area being considered for designation.

(c) Primary care professional(s) in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers, such as:

(i) Significant differences between the demographic (or socio-economic) characteristics of the area under consideration and those of the contiguous area, indicating that the population of the area under consideration may be effectively isolated from nearby resources. This isolation could be indicated, for example, by an unusually high proportion of non-English-speaking persons.

(ii) A lack of economic access to contiguous area resources, as indicated particularly where a very high proportion of the population of the area under consideration is poor (*i.e.*, where more than 20 percent of the population or the households have incomes below the poverty level), and Medicaid-covered or public primary care services are not available in the contiguous area.

**C. Determination of Degree of Shortage.**

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of full-time equivalent primary care physicians and the presence or absence of unusually high needs for primary health care services, according to the following table:

	High needs not indicated	High needs indicated
Group 1 ....	No physicians .....	No physicians; or R $\geq$ 5,000
Group 2 ....	R $\geq$ 5,000 .....	5,000>R $\geq$ 4,000
Group 3 ....	5,000>R $\geq$ 4,000 .....	4,000>R $\geq$ 3,500
Group 4 ....	4,000>R $\geq$ 3,500 .....	3,500>R $\geq$ 3,000

**D. Determination of size of primary care physician shortage.** Size of Shortage (in number of FTE primary care physicians needed) will be computed using the following formulas:

(1) For areas without unusually high need or insufficient capacity:

Primary care physician shortage=area population/3,500 – number of FTE primary care physicians

(2) For areas with unusually high need or insufficient capacity:

Primary care physician shortage=area population/3,000 – number of FTE primary care physicians

**Part II—Population Groups**

**A. Criteria.**

1. In general, specific population groups within particular geographic areas will be designated as having a shortage of primary medical care professional(s) if the following three criteria are met:

(a) The area in which they reside is rational for the delivery of primary medical care services, as defined in paragraph B.1 of part I of this appendix.

(b) Access barriers prevent the population group from use of the area's primary medical care providers. Such barriers may be economic, linguistic, cultural, or architectural, or could involve refusal of some providers to accept certain types of patients or to accept Medicaid reimbursement.

(c) The ratio of the number of persons in the population group to the number of primary care physicians practicing in the area and serving the population group is at least 3,000:1.

2. Indians and Alaska Natives will be considered for designation as having shortages of primary care professional(s) as follows:

(a) Groups of members of Indian tribes (as defined in section 4(d) of Pub. L. 94-437, the Indian Health Care Improvement Act of 1976) are automatically designated.

(b) Other groups of Indians or Alaska Natives (as defined in section 4(c) of Pub. L. 94-437) will be designated if the general criteria in paragraph A are met.

**B. Determination of Degree of Shortage.**

Each designated population group will be assigned to a degree-of-shortage group, based on the ratio (R) of the group's population to the number of primary care physicians serving it, as follows:

Group 1—No physicians or R>5,000.

Group 2—5,000>R $\geq$ 4,000.

Group 3—4,000>R $\geq$ 3,500.

Group 4—3,500>R $\geq$ 3,000.

Population groups which have received "automatic" designation will be assigned to degree-of-shortage group 4 if no information on the ratio of the number of persons in the group to the number of FTE primary care physicians serving them is provided.

**C. Determination of size of primary care physician shortage.** Size of shortage (in number of primary care physicians needed) will be computed as follows:

Primary care physician shortage=number of persons in population group/3,000 – number of FTE primary care physicians

**Part III—Facilities**

**A. Federal and State Correctional Institutions.**

**1. Criteria.**

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of primary medical care professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE primary care physicians serving the institution is at least 1,000:1. (Here the number of internees is the number of inmates present at the beginning of the year plus the number of new inmates entering the institution during the year, including those who left before the end of the year; the number of FTE primary care physicians is computed as in part I, section B, paragraph 3 above.)

**2. Determination of Degree of Shortage.**

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to primary care physicians, as follows:

Group 1—Institutions with 500 or more inmates and no physicians.

Group 2—Other institutions with no physicians and institutions with R $\geq$ 2,000.



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Group 3—Institutions with 2,000>R≥1,000.

### B. Public or Non-Profit Medical Facilities. 1. Criteria.

Public or non-profit private medical facilities will be designated as having a shortage of primary medical care professional(s) if:

(a) the facility is providing primary medical care services to an area or population group designated as having a primary care professional(s) shortage; and

(b) the facility has insufficient capacity to meet the primary care needs of that area or population group.

### 2. Methodology

In determining whether public or nonprofit private medical facilities meet the criteria established by paragraph B.1 of this Part, the following methodology will be used:

(a) *Provision of Services to a Designated Area or Population Group.*

A facility will be considered to be providing services to a designated area or population group if either:

(i) A majority of the facility's primary care services are being provided to residents of designated primary care professional(s) shortage areas or to population groups designated as having a shortage of primary care professional(s); or

(ii) The population within a designated primary care shortage area or population group has reasonable access to primary care services provided at the facility. Reasonable access will be assumed if the area within which the population resides lies within 30 minutes travel time of the facility and non-physical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

Migrant health centers (as defined in section 319(a)(1) of the Act) which are located in areas with designated migrant population groups and Indian Health Service facilities are assumed to be meeting this requirement.

(b) *Insufficient capacity to meet primary care needs.*

A facility will be considered to have insufficient capacity to meet the primary care needs of the area or population it serves if at least two of the following conditions exist at the facility:

(i) There are more than 8,000 outpatient visits per year per FTE primary care physician on the staff of the facility. (Here the number of FTE primary care physicians is computed as in Part I, Section B, paragraph 3 above.)

(ii) There is excessive usage of emergency room facilities for routine primary care.

(iii) Waiting time for appointments is more than 7 days for established patients or more than 14 days for new patients, for routine health services.

(iv) Waiting time at the facility is longer than 1 hour where patients have appoint-

ments or 2 hours where patients are treated on a first-come, first-served basis.

### 3. Determination of Degree of Shortage.

Each designated medical facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8737, Mar. 2, 1989; 57 FR 2480, Jan. 22, 1992]

## APPENDIX B TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF DENTAL PROFESSIONAL(S)

### Part I—Geographic Areas

#### A. Federal and State Correctional Institutions.

##### 1. Criteria

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of dental professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE dentists serving the institution is at least 1,500:1.

Here the number of internees is defined as follows:

(i) If the number of new inmates per year and the average length-of-stay are not specified, or if the information provided does not indicate that intake dental examinations are routinely performed by dentists upon entry, then—Number of internees=average number of inmates.

(ii) If the average length-of-stay is specified as one year or more, and intake dental examinations are routinely performed upon entry, then—Number of internees=average number of inmates+number of new inmates per year.

(iii) If the average length-of-stay is specified as less than one year, and intake dental examinations are routinely performed upon entry, then—Number of internees=average number of inmates+ $\frac{1}{3} \times (1+2 \times \text{ALOS}) \times$  number of new inmates per year where ALOS=average length-of-stay (in fraction of year).

(The number of FTE dentists is computed as in part I, section B, paragraph 3 above.)

##### 2. Determination of Degree of Shortage.

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to dentists, as follows:

Group 1—Institutions with 500 or more inmates and no dentists.

Group 2—Other institutions with no dentists and institutions with R greater than (or equal to) 3,000:1.

Group 3—Institutions with R greater than (or equal to) 1,500:1 but less than 3,000:1.

**B. Methodology.**

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

**1. Rational Area for the Delivery of Dental Services.**

(a) The following areas will be considered rational areas for the delivery of dental health services:

(i) A county, or a group of several contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county (or an area made up of portions of more than one county) whose population, because of topography, market or transportation patterns, distinctive population characteristics, or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to such resources.

(iii) Established neighborhoods and communities within metropolitan areas which display a strong self-identity (as indicated by a homogenous socioeconomic or demographic structure and/or a traditional of interaction or intradependency), have limited interaction with contiguous areas, and which, in general, have a minimum population of 20,000.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

**2. Population Count.**

The population count use will be the total permanent resident civilian population of the area, excluding inmates of institutions, with the following adjustments:

(a) Seasonal residents, i.e., those who maintain a residence in the area but inhabit it for only 2 to 8 months per year, may be included but must be weighted in proportion to the fraction of the year they are present in the area.

(b) Migratory workers and their families may be included in an area's population using the following formula: Effective migrant contribution to population=(fraction of year migrants are present in area)×(average daily number of migrants during portion of year that migrants are present).

**3. Counting of Dental Practitioners.**

(a) All non-Federal dentists providing patient care will be counted, except in those areas where it is shown that specialists (those dentists not in general practice or pedodontics) are serving a larger area and are not addressing the general dental care needs of the area under consideration.

(b) Full-time equivalent (FTE) figures will be used to reflect productivity differences among dental practices based on the age of the dentists, the number of auxiliaries employed, and the number of hours worked per week. In general, the number of FTE dentists will be computed using weights obtained from the matrix in Table 1, which is based on the productivity of dentists at various ages, with different numbers of auxiliaries, as compared with the average productivity of all dentists. For the purposes of these determinations, an auxiliary is defined as any non-dentist staff employed by the dentist to assist in operation of the practice.

**TABLE 1—EQUIVALENCY WEIGHTS, BY AGE AND NUMBER OF AUXILIARIES**

	<55	55–59	60–64	65+
No auxiliaries .....	0.8	0.7	0.6	0.5
One auxiliary .....	1.0	0.9	0.8	0.7
Two auxiliaries .....	1.2	1.0	1.0	0.8
Three auxiliaries .....	1.4	1.2	1.0	1.0
Four or more auxiliaries ....	1.5	1.5	1.3	1.2

If information on the number of auxiliaries employed by the dentist is not available, Table 2 will be used to compute the number of full-time equivalent dentists.

**TABLE 2—EQUIVALENCY WEIGHTS, BY AGE**

	55	55–59	60–64	65+
Equivalency weights .....	1.2	0.9	0.8	0.6

The number of FTE dentists within a particular age group (or age/auxiliary group) will be obtained by multiplying the number of dentists within that group by its corresponding equivalency weight. The total supply of FTE dentists within an area is then computed as the sum of those dentists within each age (or age/auxiliary) group.

(c) The equivalency weights specified in tables 1 and 2 assume that dentists within a particular group are working full-time (40 hours per week). Where appropriate data are available, adjusted equivalency figures for dentists who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who are available to the population of an area only on a part-time basis will be used to reflect the reduced availability of these dentists. In computing these equivalency figures, every 4 hours (or ½ day) spent in the dental practice will be counted as 0.1 FTE except that each dentist working more than 40 hours a week will be

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counted as 1.0. The count obtained for a particular age group of dentists will then be multiplied by the appropriate equivalency weight from table 1 or 2 to obtain a full-time equivalent figure for dentists within that particular age or age/auxiliary category.

### 4. Determination of Unusually High Needs for Dental Services.

An area will be considered as having unusually high needs for dental services if at least one of the following criteria is met:

(a) More than 20% of the population (or of all households) has incomes below the poverty level.

(b) The majority of the area's population does not have a fluoridated water supply.

### 5. Determination of Insufficient Capacity of Existing Dental Care Providers.

An area's existing dental care providers will be considered to have insufficient capacity if at least two of the following criteria are met:

(a) More than 5,000 visits per year per FTE dentist serving the area.

(b) Unusually long waits for appointments for routine dental services (*i.e.*, more than 6 weeks).

(c) A substantial proportion (2% or more) of the area's dentists do not accept new patients.

### 6. Contiguous Area Considerations.

Dental professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, over-utilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Dental professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with Paragraph B.1.(b) of this part).

(b) Contiguous area population-to-(FTE) dentist ratios are in excess of 3,000:1, indicating that resources in contiguous areas cannot be expected to help alleviate the shortage situation in the area being considered for designation.

(c) Dental professional(s) in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers, such as:

(i) Significant differences between the demographic (or socioeconomic) characteristics of the area under consideration and those of the contiguous area, indicating that the population of the area under consideration may be effectively isolated from nearby resources. Such isolation could be indicated, for example, by an unusually high proportion of non-English-speaking persons.

(ii) A lack of economic access to contiguous area resources, particularly where a very high proportion of the population of the area under consideration is poor (*i.e.*, where more than 20 percent of the population or of

the households have incomes below the poverty level) and Medicaid-covered or public dental services are not available in the contiguous area.

### C. Determination of Degree of Shortage.

The degree of shortage of a given geographic area, designated as having a shortage of dental professional(s), will be determined using the following procedure:

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of full-time-equivalent dentists and the presence or absence of unusually high needs for dental services, or insufficient capacity of existing dental care providers according to the following table:

	High needs or insufficient capacity not indicated	High needs or insufficient capacity indicated
Group 1 ....	No dentists .....	No dentists or R $\geq$ 8,000.
Group 2 ....	R $\geq$ 8,000 .....	8,000>R $\geq$ 6,000.
Group 3 ....	8,000>R $\geq$ 6,000 .....	6,000>R $\geq$ 5,000.
Group 4 ....	6,000>R $\geq$ 5,000 .....	5,000>R $\geq$ 4,000.

### D. Determination of size of dental shortage.

Size of Dental Shortage (in number of FTE dental practitioners needed) will be computed using the following formulas:

(1) For areas without unusually high need:  
Dental shortage=area population/  
5,000 – number of FTE dental practitioners

(2) For areas with unusually high need:  
Dental shortage=area population/  
4,000 – number of FTE dental practitioners

## Part II—Population Groups

### A. Criteria.

1. In general, specified population groups within particular geographic areas will be designated as having a shortage of dental care professional(s) if the following three criteria are met:

a. The area in which they reside is rational for the delivery of dental care services, as defined in paragraph B.1 of part I of this appendix.

b. Access barriers prevent the population group from use of the area's dental providers.

c. The ratio (R) of the number of persons in the population group to the number of dentists practicing in the area and serving the population group is at least 4,000:1.

2. Indians and Alaska Natives will be considered for designation as having shortages of dental professional(s) as follows:

(a) Groups of members of Indian tribes (as defined in section 4(d) of Pub. L. 94-437, the Indian Health Care Improvement Act of 1976) are automatically designated.

(b) Other groups of Indians or Alaska Natives (as defined in section 4(c) of Pub. L. 94-437) will be designated if the general criteria in paragraph 1 are met.

*B. Determination of Degree of Shortage.*

Each designated population group will be assigned to a degree-of-shortage group as follows:

- Group 1—No dentists or  $R \geq 8,000$ .
- Group 2— $8,000 > R \geq 6,000$ .
- Group 3— $6,000 > R \geq 5,000$ .
- Group 4— $5,000 > R \geq 4,000$ .

Population groups which have received “automatic” designation will be assigned to degree-of-shortage group 4 unless information on the ratio of the number of persons in the group to the number of FTE dentists serving them is provided.

*C. Determination of size of dental shortage.*

Size of dental shortage will be computed as follows:

Dental shortage = number of persons in population group/4,000 – number of FTE dental practitioners

*Part III—Facilities**A. Federal and State Correctional Institutions.**1. Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of dental professional(s) if both the following criteria are met:

- (a) The institution has at least 250 inmates.
- (b) The ratio of the number of internees per year to the number of FTE dentists serving the institution is at least 1,500:1. (Here the number of internees is the number of inmates present at the beginning of the year plus the number of new inmates entering the institution during the year, including those who left before the end of the year; the number of FTE dentists is computed as in part I, section B, paragraph 3 above.)

*2. Determination of Degree-of-Shortage.*

Designated correctional institutions will be assigned to degree-of-shortage groups as follows, based on number of inmates and/or the ratio (R) of internees to dentists:

- Group 1—Institutions with 500 or more inmates and no dentists.
- Group 2—Other institutions with no dentists and institutions with  $R > 3,000$ .
- Group 3—Institutions with  $3,000 > R > 1,500$ .

*B. Public or Non-Profit Private Dental Facilities.**1. Criteria.*

Public or nonprofit private facilities providing general dental care services will be designated as having a shortage of dental professional(s) if both of the following criteria are met:

- (a) The facility is providing general dental care services to an area or population group designated as having a dental professional(s) shortage; and

- (b) The facility has insufficient capacity to meet the dental care needs of that area or population group.

*2. Methodology.*

In determining whether public or nonprofit private facilities meet the criteria established by paragraph B.1. of this part, the following methodology will be used:

*(a) Provision of Services to a Designated Area or Population Group.*

A facility will be considered to be providing services to an area or population group if either:

- (i) A majority of the facility’s dental care services are being provided to residents of designated dental professional(s) shortage areas or to population groups designated as having a shortage of dental professional(s); or

- (ii) The population within a designated dental shortage area or population group has reasonable access to dental services provided at the facility. Reasonable access will be assumed if the population lies within 40 minutes travel time of the facility and non-physical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

Migrant health centers (as defined in section 319(a)(1) of the Act) which are located in areas with designated migrant population groups and Indian Health Service facilities are assumed to be meeting this requirement.

*(b) Insufficient Capacity To Meet Dental Care Needs.*

A facility will be considered to have insufficient capacity to meet the dental care needs of a designated area or population group if either of the following conditions exists at the facility.

- (i) There are more than 5,000 outpatient visits per year per FTE dentist on the staff of the facility. (Here the number of FTE dentists is computed as in part I, section B, paragraph 3 above.)
- (ii) Waiting time for appointments is more than 6 weeks for routine dental services.

*3. Determination of Degree of Shortage.*

Each designated dental facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8738, Mar. 2, 1989; 57 FR 2480, Jan. 22, 1992]

## APPENDIX C TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF MENTAL HEALTH PROFESSIONALS

*Part I—Geographic Areas*

*A. Criteria.* A geographic area will be designated as having a shortage of mental health professionals if the following four criteria are met:

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1. The area is a rational area for the delivery of mental health services.

2. One of the following conditions prevails within the area:

(a) The area has—

(i) A population-to-core-mental-health-professional ratio greater than or equal to 6,000:1 and a population-to-psychiatrist ratio greater than or equal to 20,000:1, or

(ii) A population-to-core-professional ratio greater than or equal to 9,000:1, or

(iii) A population-to-psychiatrist ratio greater than or equal to 30,000:1;

(b) The area has unusually high needs for mental health services, and has—

(i) A population-to-core-mental-health-professional ratio greater than or equal to 4,500:1 and

A population-to-psychiatrist ratio greater than or equal to 15,000:1, or

(ii) A population-to-core-professional ratio greater than or equal to 6,000:1, or

(iii) A population-to-psychiatrist ratio greater than or equal to 20,000:1;

3. Mental health professionals in contiguous areas are overutilized, excessively distant or inaccessible to residents of the area under consideration.

### B. Methodology.

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Mental Health Services.*

(a) The following areas will be considered rational areas for the delivery of mental health services:

(i) An established mental health catchment area, as designated in the State Mental Health Plan under the general criteria set forth in section 238 of the Community Mental Health Centers Act.

(ii) A portion of an established mental health catchment area whose population, because of topography, market and/or transportation patterns or other factors, has limited access to mental health resources in the rest of the catchment area, as measured generally by a travel time of greater than 40 minutes to these resources.

(iii) A county or metropolitan area which contains more than one mental health catchment area, where data are unavailable by individual catchment area.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the

distance corresponding to 40 minutes travel time.

### 2. Population Count.

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions.

3. *Counting of mental health professionals.* (a) All non-Federal core mental health professionals (as defined below) providing mental health patient care (direct or other, including consultation and supervision) in ambulatory or other short-term care settings to residents of the area will be counted. Data on each type of core professional should be presented separately, in terms of the number of full-time-equivalent (FTE) practitioners of each type represented.

(b) Definitions:

(i) *Core mental health professionals or core professionals* includes those psychiatrists, clinical psychologists, clinical social workers, psychiatric nurse specialists, and marriage and family therapists who meet the definitions below.

(ii) *Psychiatrist* means a doctor of medicine (M.D.) or doctor of osteopathy (D.O.) who

(A) Is certified as a psychiatrist or child psychiatrist by the American Medical Specialties Board of Psychiatry and Neurology or by the American Osteopathic Board of Neurology and Psychiatry, or, if not certified, is "broad-eligible" (i.e., has successfully completed an accredited program of graduate medical or osteopathic education in psychiatry or child psychiatry); and

(B) Practices patient care psychiatry or child psychiatry, and is licensed to do so, if required by the State of practice.

(iii) *Clinical psychologist* means an individual (normally with a doctorate in psychology) who is practicing as a clinical or counseling psychologist and is licensed or certified to do so by the State of practice; or, if licensure or certification is not required in the State of practice, an individual with a doctorate in psychology and two years of supervised clinical or counseling experience. (School psychologists are not included.)

(iv) *Clinical social worker* means an individual who—

(A) Is certified as a clinical social worker by the American Board of Examiners in Clinical Social Work, or is listed on the National Association of Social Workers' Clinical Register, or has a master's degree in social work and two years of supervised clinical experience; and

(B) Is licensed to practice as a social worker, if required by the State of practice.

(v) *Psychiatric nurse specialist* means a registered nurse (R.N.) who—

(A) Is certified by the American Nurses Association as a psychiatric and mental health clinical nurse specialist, or has a master's degree in nursing with a specialization in psychiatric/mental health and two years of supervised clinical experience; and

(B) Is licensed to practice as a psychiatric or mental health nurse specialist, if required by the State of practice.

(vi) *Marriage and family therapist* means an individual (normally with a master's or doctoral degree in marital and family therapy and at least two years of supervised clinical experience) who is practicing as a marital and family therapist and is licensed or certified to do so by the State of practice; or, if licensure or certification is not required by the State of practice, is eligible for clinical membership in the American Association for Marriage and Family Therapy.

(c) Practitioners who provide patient care to the population of an area only on a part-time basis (whether because they maintain another office elsewhere, spend some of their time providing services in a facility, are semi-retired, or operate a reduced practice for other reasons), will be counted on a partial basis through the use of full-time-equivalency calculations based on a 40-hour week. Every 4 hours (or ½ day) spent providing patient care services in ambulatory or inpatient settings will be counted as 0.1 FTE, and each practitioner providing patient care for 40 or more hours per week as 1.0 FTE. Hours spent on research, teaching, vocational or educational counseling, and social services unrelated to mental health will be excluded; if a practitioner is located wholly or partially outside the service area, only those services actually provided within the area are to be counted.

(d) In some cases, practitioners located within an area may not be accessible to the general population of the area under consideration. Practitioners working in restricted facilities will be included on an FTE basis based on time spent outside the facility. Examples of restricted facilities include correctional institutions, youth detention facilities, residential treatment centers for emotionally disturbed or mentally retarded children, school systems, and inpatient units of State or county mental hospitals.

(e) In cases where there are mental health facilities or institutions providing both inpatient and outpatient services, only those FTEs providing mental health services in outpatient units or other short-term care units will be counted.

(f) Adjustments for the following factors will also be made in computing the number of FTE providers:

(i) Practitioners in residency programs will be counted as 0.5 FTE.

(ii) Graduates of foreign schools who are not citizens or lawful permanent residents of the United States will be excluded from counts.

(iii) Those graduates of foreign schools who are citizens or lawful permanent residents of the United States, and practice in certain settings, but do not have unrestricted licenses to practice, will be counted on a full-

time-equivalency basis up to a maximum of 0.5 FTE.

(g) Practitioners suspended for a period of 18 months or more under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act will not be counted.

4. *Determination of unusually high needs for mental health services.* An area will be considered to have unusually high needs for mental health services if one of the following criteria is met:

(a) 20 percent of the population (or of all households) in the area have incomes below the poverty level.

(b) The youth ratio, defined as the ratio of the number of children under 18 to the number of adults of ages 18 to 64, exceeds 0.6.

(c) The elderly ratio, defined as the ratio of the number of persons aged 65 and over to the number of adults of ages 18 to 64, exceeds 0.25.

(d) A high prevalence of alcoholism in the population, as indicated by prevalence data showing the area's alcoholism rates to be in the worst quartile of the nation, region, or State.

(e) A high degree of substance abuse in the area, as indicated by prevalence data showing the area's substance abuse to be in the worst quartile of the nation, region, or State.

5. *Contiguous area considerations.* Mental health professionals in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Core mental health professionals in the contiguous area are more than 40 minutes travel time from the closest population center of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The population-to-core-mental-health-professional ratio in the contiguous area is in excess of 3,000:1 and the population-to-psychiatrist ratio there is in excess of 10,000:1, indicating that core mental health professionals in the contiguous areas are overutilized and cannot be expected to help alleviate the shortage situation in the area for which designation is being considered. (If data on core mental health professionals other than psychiatrists are not available for the contiguous area, a population-to-psychiatrist ratio there in excess of 20,000:1 may be used to demonstrate overutilization.)

(c) Mental health professionals in contiguous areas are inaccessible to the population of the requested area due to geographic, cultural, language or other barriers or because of residency restrictions of programs or facilities providing such professionals.

C. *Determination of degree of shortage.* Designated areas will be assigned to degree-of-

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shortage groups according to the following table, depending on the ratio ( $R_C$ ) of population to number of FTE core-mental-health-service providers ( $FTE_C$ ); the ratio ( $R_P$ ) of population to number of FTE psychiatrists ( $FTE_P$ ); and the presence or absence of high needs:

### High Needs Not Indicated

- Group 1— $FTE_C=0$  and  $FTE_P=0$
- Group 2— $R_C$  gte  $6,000:1$  and  $FTE_P=0$
- Group 3— $R_C$  gte  $6,000:1$  and  $R_P$  gte  $20,000$
- Group 4(a)—For psychiatrist placements only: All other areas with  $FTE_P=0$  or  $R_P$  gte  $30,000$
- Group 4(b)—For other mental health practitioner placements: All other areas with  $R_C$  gte  $9,000:1$ .

\*Note: "gte" means "greater than or equal to".

### High Needs Indicated

- Group 1— $FTE_C=0$  and  $FTE_P=0$
- Group 2— $R_C$  gte  $4,500:1$  and  $FTE_P=0$
- Group 3— $R_C$  gte  $4,500:1$  and  $R_P$  gte  $15,000$
- Group 4(a)—For psychiatrist placements only: All other areas with  $FTE_P=0$  or  $R_P$  gte  $20,000$
- Group 4(b)—For other mental health practitioner placements: All other areas with  $R_C$  gte  $6,000:1$ .

D. *Determination of Size of Shortage.* Size of Shortage (in number of FTE professionals needed) will be computed using the following formulas:

- (1) For areas without unusually high need:  
Core professional shortage=area population/  
 $6,000$ —number of FTE core professionals  
Psychiatrist shortage=area population/  
 $20,000$ —number of FTE psychiatrists
- (2) For areas with unusually high need:  
Core professional shortage=area population/  
 $4,500$ —number of FTE core professionals  
Psychiatrist shortage=area population/  
 $15,000$ —number of FTE psychiatrists

### Part II—Population Groups

A. *Criteria.* Population groups within particular rational mental health service areas will be designated as having a mental health professional shortage if the following criteria are met:

- 1. Access barriers prevent the population group from using those core mental health professionals which are present in the area; and
- 2. One of the following conditions prevails:
  - (a) The ratio of the number of persons in the population group to the number of FTE core mental health professionals serving the population group is greater than or equal to  $4,500:1$  and the ratio of the number of persons in the population group to the number of FTE psychiatrists serving the population group is greater than or equal to  $15,000:1$ ; or,

- (b) The ratio of the number of persons in the population group to the number of FTE core mental health professionals serving the population group is greater than or equal to  $6,000:1$ ; or,

- (c) The ratio of the number of persons in the population group to the number of FTE psychiatrists serving the population group is greater than or equal to  $20,000:1$ .

B. *Determination of degree of shortage.* Designated population groups will be assigned to the same degree-of-shortage groups defined in part I.C of this appendix for areas with unusually high needs for mental health services, using the computed ratio ( $R_C$ ) of the number of persons in the population group to the number of FTE core mental health service providers ( $FTE_C$ ) serving the population group, and the ratio ( $R_P$ ) of the number of persons in the population group to the number of FTE psychiatrists ( $FTE_P$ ) serving the population group.

C. *Determination of size of shortage.* Size of shortage will be computed as follows:

Core professional shortage=number of persons in population group/ $4,500$ —number of FTE core professionals

Psychiatrist shortage=number of persons in population group/ $15,000$ —number of FTE psychiatrists

### Part III—Facilities

#### A. Federal and State Correctional Institutions

##### 1. Criteria.

Medium to maximum security Federal and State correctional institutions for adults or youth, and youth detention facilities, will be designated as having a shortage of psychiatric professional(s) if both of the following criteria are met:

- (a) The institution has more than 250 inmates, and

- (b) The ratio of the number of internees per year to the number of FTE psychiatrists serving the institution is at least  $2,000:1$ . (Here the number of internees is the number of inmates or residents present at the beginning of the year, plus the number of new inmates or residents entering the institution during the year, including those who left before the end of the year; the number of FTE psychiatrists is computed as in part I, section B, paragraph 3 above.)

##### 2. Determination of Degree of Shortage.

Correctional facilities and youth detention facilities will be assigned to degree-of-shortage groups, based on the number of inmates and/or the ratio (R) of internees to FTE psychiatrists, as follows:

Group 1—Facilities with 500 or more inmates or residents and no psychiatrist.

Group 2—Other facilities with no psychiatrists and facilities with 500 or more inmates or residents and  $R>3,000$ .

Group 3—All other facilities.

#### B. State and County Mental Hospitals.

1. *Criteria.*

A State or county hospital will be designated as having a shortage of psychiatric professional(s) if both of the following criteria are met:

(a) The mental hospital has an average daily inpatient census of at least 100; and

(b) The number of workload units per FTE psychiatrists available at the hospital exceeds 300, where workload units are calculated using the following formula:

Total workload units = average daily inpatient census +  $2 \times$  (number of inpatient admissions per year) +  $0.5 \times$  (number of admissions to day care and outpatient services per year).

2. *Determination of Degree of Shortage.*

State or county mental hospitals will be assigned to degree-of-shortage groups, based on the ratio (R) of workload units to number of FTE psychiatrists, as follows:

Group 1—No psychiatrists, or  $R > 1,800$ .

Group 2— $1,800 > R > 1,200$ .

Group 3— $1,200 > R > 600$ .

Group 4— $600 > R > 300$ .

C. *Community Mental Health Centers and Other Public or Nonprofit Private Facilities.*1. *Criteria.*

A community mental health center (CMHC), authorized by Pub. L. 94–63, or other public or nonprofit private facility providing mental health services to an area or population group, may be designated as having a shortage of psychiatric professional(s) if the facility is providing (or is responsible for providing) mental health services to an area or population group designated as having a mental health professional(s), and the facility has insufficient capacity to meet the psychiatric needs of the area or population group.

2. *Methodology.*

In determining whether CMHCs or other public or nonprofit private facilities meet the criteria established in paragraph C.1 of this Part, the following methodology will be used.

(a) *Provision of Services to a Designated Area or Population Group.*

The facility will be considered to be providing services to a designated area or population group if either:

(i) A majority of the facility's mental health services are being provided to residents of designated mental health professional(s) shortage areas or to population groups designated as having a shortage of mental health professional(s); or

(ii) The population within a designated psychiatric shortage area or population group has reasonable access to mental health services provided at the facility. Such reasonable access will be assumed if the population lies within 40 minutes travel time of the facility and nonphysical barriers (relating to demographic and socioeconomic char-

acteristics of the population) do not prevent the population from receiving care at the facility.

(b) *Responsibility for Provision of Services.*

This condition will be considered to be met if the facility, by Federal or State statute, administrative action, or contractual agreement, has been given responsibility for providing and/or coordinating mental health services for the area or population group, consistent with applicable State plans.

(c) *Insufficient capacity to meet mental health service needs.* A facility will be considered to have insufficient capacity to meet the mental health service needs of the area or population it serves if:

(i) There are more than 1,000 patient visits per year per FTE core mental health professional on staff of the facility, or

(ii) There are more than 3,000 patient visits per year per FTE psychiatrist on staff of the facility, or

(iii) No psychiatrists are on the staff and this facility is the only facility providing (or responsible for providing) mental health services to the designated area or population.

3. *Determination of Degree-of-Shortage.*

Each designated facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8738, Mar. 2, 1989; 57 FR 2477, Jan. 22, 1992]

## APPENDIX D TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VISION CARE PROFESSIONAL(S)

## Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of vision care professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of vision care services.

2. The estimated number of optometric visits supplied by vision care professional(s) in the area is less than the estimated requirements of the area's population for these visits, and the computed shortage is at least 1,500 optometric visits.

3. Vision care professional(s) in contiguous areas are excessively distant, overutilized, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Vision Care Services.*



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(a) The following areas will be considered rational areas for the delivery of vision care services:

(i) A county, or a group of contiguous counties whose population centers are within 40 minutes travel time of each other;

(ii) A portion of a county (or an area made up of portions of more than one county) whose population, because of topography, market or transportation patterns, or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

### 2. Determination of Estimated Requirement for Optometric Visits.

The number of optometric visits required by an area's population will be estimated by multiplying each of the following visit rates by the size of the population within that particular age group and then adding the figures obtained together.

Age	Annual number of optometric visits required per person, by age					
	Under 20	20-29	30-39	40-49	50-59	60 and over
Number of visits .....	0.11	0.20	0.24	0.35	0.41	0.48

For geographic areas where the age distribution of the population is not known, it will be assumed that the percentage distribution, by age groups, for the area is the same as the distribution for the county of which it is a part.

### (3) Determination of Estimated Supply of Optometric Visits.

The estimated supply of optometric services will be determined by use of the following formula:

Optometric visits supplied = 3,000 × (number of optometrists under 65)

Optometric visits supplied + 2,000 × (number of optometrists 65 and over)

Optometric visits supplied + 1,500 × (number of ophthalmologists)

### (4) Determination of Size of Shortage.

Size of shortage (in number of optometric visits) will be computed as follows:

Optometric visit shortage = visits required – visits supplied

### (5) Contiguous Area Considerations.

Vision care professional(s) in area contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area if one of the following conditions prevails in each contiguous area:

(a) Vision care professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The estimated requirement for vision care services in the contiguous area exceeds the estimated supply of such services there, based on the requirements and supply calculations previously described.

(c) Vision care professional(s) in the contiguous area are inaccessible to the population of the area because of specified access barriers (such as economic or cultural barriers).

### C. Determination of Degree-of-Shortage.

Designated areas (and population groups) will be assigned to degree-of-shortage groups, based on the ratio of optometric visits supplied to optometric visits required for the area (or group), as follows:

Group 1—Areas (or groups) with no optometric visits being supplied (i.e., with no optometrists or ophthalmologists).

Group 2—Areas (or groups) where the ratio of optometric visits supplied to optometric visits required is less than 0.5.

Group 3—Areas (or groups) where the ratio of optometric visits supplied to optometric visits required is between 0.5 and 1.0.

## Part II—Population Groups

### A. Criteria.

Population groups within particular geographic areas will be designated if both the following criteria are met:

(1) Members of the population group do not have access to vision care resources within the area (or in contiguous areas) because of non-physical access barriers (such as economic or cultural barriers).

(2) The estimated number of optometric visits supplied to the population group (as determined under paragraph B.3 of part I of this Appendix) is less than the estimated number of visits required by that group (as determined under paragraph B.2 of part I of this Appendix), and the computed shortage is at least 1,500 optometric visits.

*B. Determination of Degree of Shortage.*

The degree of shortage of a given population group will be determined in the same way as described for areas in paragraph C of part I of this appendix.

APPENDIX E TO PART 5—CRITERIA FOR  
DESIGNATION OF AREAS HAVING  
SHORTAGES OF PODIATRIC PROFES-  
SIONAL(S)

*Part I—Geographic Areas**A. Criteria.*

A geographic area will be designated as having a shortage of podiatric professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of podiatric services.
2. The area's ratio of population to foot care practitioners is at least 28,000:1, and the computed podiatrist shortage to meet this ratio is at least 0.5.
3. Podiatric professional(s) in contiguous areas are overutilized, excessively distant, or inaccessible to the population of the area under consideration.

*B. Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

*1. Rational Areas for the Delivery of Podiatric Services.*

(a) The following areas will be considered rational areas for the delivery of podiatric services:

- (i) A county or a group of contiguous counties whose population centers are within 40 minutes travel time of each other.
- (ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market and/or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes from its population center to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

- (i) Under normal conditions with primary roads available: 25 miles.
- (ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.
- (iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the area corresponding to 40 minutes travel time.

*2. Population Count.*

The population count used will be the total permanent resident civilian population of

the area, excluding inmates of institutions, adjusted by the following formula to take into account the differing utilization rates of podiatric services by different age groups within the population:

Adjusted population = total population  $\times$  (1 + 2.2  $\times$  (percent of population 65 and over) – 0.44  $\times$  (percent of population under 17)).

*3. Counting of Foot Care Practitioners.*

(a) All podiatrists providing patient care will be counted. However, in order to take into account productivity differences in podiatric practices associated with the age of the podiatrists, the following formula will be utilized:

Number of FTE podiatrists = 1.0  $\times$  (podiatrists under age 55)  
+ .8  $\times$  (podiatrists age 55 and over)

(b) In order to take into account the fact that orthopedic surgeons and general and family practitioners devote a percentage of their time to foot care, the total available foot care practitioners will be computed as follows:

Number of foot care practitioners = number of FTE podiatrists  
+ .15  $\times$  (number of orthopedic surgeons)  
+ .02  $\times$  (number of general and family practitioners).

*4. Determination of Size of Shortage.*

Size of shortage (in number of FTE podiatrists) will be computed as follows:

Podiatrist shortage = adjusted population/28,000 – number of FTE foot care practitioners.

*5. Contiguous Area Considerations.*

Podiatric professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Podiatric professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation.

(b) The population-to-foot care practitioner ratio in the contiguous areas is in excess of 20,000:1, indicating that contiguous area podiatric professional(s) cannot be expected to help alleviate the shortage situation in the area for which designation is requested.

(c) Podiatric professional(s) in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers (such as economic or cultural barriers).

*C. Determination of Degree of Shortage.*

Designated areas will be assigned to groups, based on the ratio (R) of adjusted population to number of foot care practitioners, as follows:

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Group 1 Areas with no foot care practitioners, and areas with  $R > 50,000$  and no podiatrists.

Group 2 Other areas with  $R > 50,000$ .

Group 3 Areas with  $50,000 > R > 28,000$ .

### APPENDIX F TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PHARMACY PROFESSIONAL(S)

#### Part I—Geographic Areas

##### A. Criteria.

A geographic area will be designated as having a shortage of pharmacy professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of pharmacy services.

2. The number of pharmacists serving the area is less than the estimated requirement for pharmacists in the area, and the computed pharmacist shortage is at least 0.5.

3. Pharmacists in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

##### B. Methodology.

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

1. *Rational Areas for the Delivery of Pharmacy Services.*

- (a) The following areas will be considered rational areas for the delivery of pharmacy services:

- (i) A county, or a group of contiguous counties whose population centers are within 30 minutes travel time of each other; and

- (ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 30 minutes to these resources.

- (b) The following distances will be used as guidelines in determining distances corresponding to 30 minutes travel time:

- (i) Under normal conditions with primary roads available: 20 miles.

- (ii) In mountainous terrain or in areas with only secondary roads available: 15 miles.

- (iii) In flat terrain or in areas connected by interstate highways: 25 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the area corresponding to 30 minutes travel time.

##### 2. Counting of Pharmacists.

All active pharmacists within the area will be counted, except those engaged in teach-

ing, administration, or pharmaceutical research.

3. *Determination of Estimated Requirement for Pharmacists.*

- (a) *Basic estimate.* The basic estimated requirement for pharmacists will be calculated as follows:

Basic pharmacist requirement =  $.15 \times (\text{resident civilian population}/1,000) + .035 \times (\text{total number of physicians engaged in patient care in the area})$ .

- (b) *Adjusted estimate.* For areas with less than 20,000 persons, the following adjustment is made to the basic estimate to compensate for the lower expected productivity of small practices.

Estimated pharmacist requirement =  $(2 - \text{population}/20,000) \times \text{basic pharmacist requirement}$ .

##### 4. Size of Shortage Computation.

The size of the shortage will be computed as follows:

Pharmacist shortage = estimated pharmacist requirement - number of pharmacists available.

##### 5. Contiguous Area Considerations.

Pharmacists in areas contiguous to an area being considered for designation will be considered excessively distant or overutilized if either:

- (a) Pharmacy professional(s) in contiguous areas are more than 30 minutes travel time from the center of the area under consideration, or

- (b) The number of pharmacists in each contiguous area is less than or equal to the estimated requirement for pharmacists for that contiguous area (as computed above).

##### C. Determination of Degree-of-Shortage.

Designated areas will be assigned to degree-of-shortage groups, based on the proportion of the estimated requirement for pharmacists which is currently available in the area, as follows:

Group 1—Areas with no pharmacists.

Group 2—Areas where the ratio of available pharmacists to pharmacists required is less than 0.5.

Group 3—Areas where the ratio of available pharmacists to pharmacists required is between 0.5 and 1.0.

### APPENDIX G TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VETERINARY PROFESSIONAL(S)

#### Part I—Geographic Areas

##### A. Criteria for Food Animal Veterinary Shortage.

A geographic area will be designated as having a shortage of food animal veterinary professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of veterinary services.

2. The ratio of veterinary livestock units to food animal veterinarians in the area is at least 10,000:1, and the computed food animal veterinarian shortage to meet this ratio is at least 0.5.

3. Food animal veterinarians in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

*B. Criteria for Companion Animal Veterinary Shortage.*

A geographic area will be designated as having a shortage of companion animal veterinary professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of veterinary services.

2. The ratio of resident civilian population to number of companion animal veterinarians in the area is at least 30,000:1 and the computed companion animal veterinary shortage to meet this ratio is at least 0.5.

3. Companion animal veterinarians in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

*C. Methodology.*

In determining whether an area meets the criteria established by paragraphs A and B of this part, the following methodology will be used:

*1. Rational Areas for the Delivery of Veterinary Services.*

(a) The following areas will be considered rational areas for the delivery of veterinary services:

(i) A county, or a group of contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county (or an area made up of portions of more than one county) which, because of topography, market and/or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

*2. Determination of Number of Veterinary Livestock Units (VLU) Requiring Care.*

Since various types of food animals require varying amounts of veterinary care, each type of animal has been assigned a weight indicating the amount of veterinary care it requires relative to that required by a milk cow. Those weights are used to compute the

number of "Veterinary Livestock Units" (VLU) for which veterinary care is required.

The VLU is computed as follows:

Veterinary Livestock Units (VLU)=(number of milk cows)

+ .2×(number of other cattle and calves)

+ .05×(number of hogs and pigs)

+ .05×(number of sheep)

+ .002×(number of poultry).

*3. Counting of Food Animal Veterinarians.*

The number of food animal veterinarians is determined by weighting the number of veterinarians within each of several practice categories according to the average fraction of practice time in that category which is devoted to food animal veterinary care, as follows:

Number of Food Animal Veterinarians=(number of veterinarians in large animal practice, exclusively)

+(number of veterinarians in bovine practice, exclusively)

+(number of veterinarians in poultry practice, exclusively)

+ .75×(mixed practice veterinarians with greater than 50% of practice in large animal care)

+ .5×(mixed practice veterinarians with approximately 50% of practice in large animal care)

+ .25×(mixed practice veterinarians with less than 50% of practice in large animal care).

*4. Counting of Companion Animal Veterinarians* (that is, those who provide services for dogs, cats, horses, and any other animals maintained as companions to the owner rather than as food animals).

The number of full-time equivalent companion animal veterinarians is determined by weighting the number of veterinarians within each of several practice categories by the average portion of their practice which is devoted to companion animal care by the practitioners within that category, as follows:

Number of Companion Animal Veterinarians=(number of veterinarians in large animal practice, exclusively)

+(number of veterinarians in equine practice, exclusively)

+ .75×(mixed practice veterinarians with greater than 50% of practice in small animal care)

+ .5×(mixed practice veterinarians with approximately 50% of practice in small animal care)

+ .25×(mixed practice veterinarians with less than 50% of practice in small animal care).

*5. Size of Shortage Computation.*

The size of shortage will be computed as follows:

(a) Food animal veterinarian shortage=(VLU/10,000)–(number of food animal veterinarians).

(b) Companion animal veterinarian shortage=(resident civilian pop./

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30,000) – (number of companion animal veterinarians).

### 6. Contiguous Area Considerations.

Veterinary professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant from the population of the area or overutilized if one of the following conditions prevails in each contiguous area:

(a) Veterinary professional(s) in the contiguous area are more than 60 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph C.1.(b) of this part).

(b) In the case of food animal veterinary professional(s), the VLU-to-food animal veterinarian ratio in the contiguous area is in excess of 5,000:1.

(c) In the case of companion animal veterinary professional(s), the population-to-companion animal veterinarian ratio in the contiguous area is in excess of 15,000:1.

### C. Determination of Degree-of-Shortage.

Designated areas will be assigned to degree-of-shortage groups as follows:

Group 1—Areas with a food animal veterinarian shortage and no veterinarians.

Group 2—Areas (not included above) with a food animal veterinarian shortage and no food animal veterinarians.

Group 3—All other food animal veterinarian shortage areas.

Group 4—All companion animal shortage areas (not included above) having no veterinarians.

Group 5—All other companion animal shortage areas.

## PART 6—FEDERAL TORT CLAIMS ACT COVERAGE OF CERTAIN GRANTEES AND INDIVIDUALS

Sec.

6.1 Applicability.

6.2 Definitions.

6.3 Eligible entities.

6.4 Covered individuals.

6.5 Deeming process for eligible entities.

6.6 Covered acts and omissions.

AUTHORITY: Sections 215 and 224 of the Public Health Service Act, 42 U.S.C. 216 and 233.

SOURCE: 60 FR 22532, May 8, 1995, unless otherwise noted.

### § 6.1 Applicability.

This part applies to entities and individuals whose acts and omissions related to the performance of medical, surgical, dental, or related functions are covered by the Federal Tort Claims Act (28 U.S.C. 1346(b) and 2671–2680) in accordance with the provisions of sec-

tion 224(g) of the Public Health Service Act (42 U.S.C. 233(g)).

### § 6.2 Definitions.

*Act* means the Public Health Service Act, as amended.

*Attorney General* means the Attorney General of the United States and any other officer or employee of the Department of Justice to whom the authority involved has been delegated.

*Covered entity* means an entity described in § 6.3 which has been deemed by the Secretary, in accordance with § 6.5, to be covered by this part.

*Covered individual* means an individual described in § 6.4.

*Effective date* as used in § 6.5 and § 6.6 refers to the date of the Secretary's determination that an entity is a covered entity.

*Secretary* means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of HHS to whom the authority involved has been delegated.

*Subrecipient* means an entity which receives a grant or a contract from a covered entity to provide a full range of health services on behalf of the covered entity.

### § 6.3 Eligible entities.

(a) *Grantees*. Entities eligible for coverage under this part are public and nonprofit private entities receiving Federal funds under any of the following grant programs:

(1) Section 329 of the Act (relating to grants for migrant health centers);

(2) Section 330 of the Act (relating to grants for community health centers);

(3) Section 340 of the Act (relating to grants for health services for the homeless); and

(4) Section 340A of the Act (relating to grants for health services for residents of public housing).

(b) *Subrecipients*. Entities that are subrecipients of grant funds described in paragraph (a) of this section are eligible for coverage only if they provide a full range of health care services on behalf of an eligible grantee and only for those services carried out under the grant funded project.

**§ 6.4 Covered individuals.**

(a) Officers and employees of a covered entity are eligible for coverage under this part.

(b) Contractors of a covered entity who are physicians or other licensed or certified health care practitioners are eligible for coverage under this part if they meet the requirements of section 224(g)(5) of the Act.

(c) An individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of a covered entity will not be covered for acts or omissions occurring after receipt by the entity employing such individual of notice of a final determination by the Attorney General that he or she is no longer covered by this part, in accordance with section 224(i) of the Act.

**§ 6.5 Deeming process for eligible entities.**

Eligible entities will be covered by this part only on and after the effective date of a determination by the Secretary that they meet the requirements of section 224(h) of the Act. In making such determination, the Secretary will receive such assurances and conduct such investigations as he or she deems necessary.

**§ 6.6 Covered acts and omissions.**

(a) Only acts and omissions occurring on and after the effective date of the Secretary's determination under § 6.5 and before the later date specified in section 224(g)(3) of the Act are covered by this part.

(b) Only claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions are covered by this part.

(c) With respect to covered individuals, only acts and omissions within the scope of their employment (or contract for services) are covered. If a covered individual is providing services which are not on behalf of the covered entity, such as on a volunteer basis or on behalf of a third-party (except as described in paragraph (d) of this section), whether for pay or otherwise, acts and omissions which are related to such services are not covered.

(d) Only acts and omissions related to the grant-supported activity of entities are covered. Acts and omissions related to services provided to individuals who are not patients of a covered entity will be covered only if the Secretary determines that:

(1) The provision of the services to such individuals benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;

(2) The provision of the services to such individuals facilitates the provision of services to patients of the entity; or

(3) Such services are otherwise required to be provided to such individuals under an employment contract or similar arrangement between the entity and the covered individual.

(e) *Examples.* The following are examples of situations within the scope of paragraph (d) of this section:

(1) A community health center deemed to be a covered entity establishes a school-based or school-linked health program as part of its grant supported activity. Even though the students treated are not necessarily registered patients of the center, the center and its health care practitioners will be covered for services provided, if the Secretary makes the determination in paragraph (d)(1) of this section.

(2) A migrant health center requires its physicians to obtain staff privileges at a community hospital. As a condition of obtaining such privileges, and thus being able to admit the center's patients to the hospital, the physicians must agree to provide occasional coverage of the hospital's emergency room. The Secretary would be authorized to determine that this coverage is necessary to facilitate the provision of services to the grantee's patients, and that it would therefore be covered by paragraph (d)(2) of this section.

(3) A homeless health services grantee makes arrangements with local community providers for after-hours coverage of its patients. The grantee's physicians are required by their employment contracts to provide periodic cross-coverage for patients of these

providers, in order to make this arrangement feasible. The Secretary may determine that the arrangement is within the scope of paragraph (d)(3) of this section.

[60 FR 22532, May. 8, 1995; 60 FR 36073, July 13, 1995]

## **PART 7—DISTRIBUTION OF REFERENCE BIOLOGICAL STANDARDS AND BIOLOGICAL PREPARATIONS**

Sec.

- 7.1 Applicability.
- 7.2 Establishment of a user charge.
- 7.3 Definitions.
- 7.4 Schedule of charges.
- 7.5 Payment procedures.
- 7.6 Exemptions.

**AUTHORITY:** Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); title V of the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701); and sec. 352 of the Public Health Service Act, as amended (42 U.S.C. 263).

**SOURCE:** 52 FR 11073, Apr. 7, 1987, unless otherwise noted.

### **§ 7.1 Applicability.**

The provisions of this part are applicable to private entities requesting from the Centers for Disease Control (CDC) reference biological standards and biological preparations for use in their laboratories.

### **§ 7.2 Establishment of a user charge.**

Except as otherwise provided in § 7.6, a user charge shall be imposed to cover the cost to CDC of producing and distributing reference biological standards and biological preparations.

### **§ 7.3 Definitions.**

*Biological standards* means a uniform and stable reference biological substance which allows measurements of relative potency to be made and described in a common currency of international and national units of activity.

*Biological preparations* means a reference biological substance which may be used for a purpose similar to that of a standard, but which has been established without a full collaborative study, or where a collaborative study has shown that it is not appropriate to establish the preparation as an international standard.

### **§ 7.4 Schedule of charges.**

The charges imposed in § 7.2 are based on the amount published in CDC's price list of available products. These charges will reflect direct costs (such as salaries and equipment), indirect costs (such as rent, telephone service, and a proportionate share of management and administrative costs), and the costs of particular ingredients. Charges may vary over time and between different biological standards or biological preparations, depending upon the cost of ingredients and the complexity of production. An up-to-date schedule of charges is available from the Biological Products Branch, Center for Infectious Diseases, Centers for Disease Control, 1600 Clifton Road, Atlanta, Georgia 30333.

### **§ 7.5 Payment procedures.**

The requester may obtain information on terms of payment and a fee schedule by writing the "Centers for Disease Control," Financial Management Office, Buckhead Facility, Room 200, Centers for Disease Control, 1600 Clifton Road, Atlanta, Georgia 30333.

### **§ 7.6 Exemptions.**

State and local health departments, governmental institutions (e.g., State hospitals and universities), the World Health Organization, and ministries of health of foreign governments may be exempted from paying user charges, when using biological standards or biological preparations for public health purposes.

## **PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS**

### **Subpart A—Accreditation**

Sec.

- 8.1 Scope.
- 8.2 Definitions.
- 8.3 Application for approval as an accreditation body.
- 8.4 Accreditation body responsibilities.
- 8.5 Periodic evaluation of accreditation bodies.
- 8.6 Withdrawal of approval of accreditation bodies.

### Subpart B—Certification and Treatment Standards

- 8.11 Opioid treatment program certification.
- 8.12 Federal opioid treatment standards.
- 8.13 Revocation of accreditation and accreditation body approval.
- 8.14 Suspension or revocation of certification.
- 8.15 Forms.

### Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

- 8.21 Applicability.
- 8.22 Definitions.
- 8.23 Limitation on issues subject to review.
- 8.24 Specifying who represents the parties.
- 8.25 Informal review and the reviewing official's response.
- 8.26 Preparation of the review file and written arguments.
- 8.27 Opportunity for oral presentation.
- 8.28 Expedited procedures for review of immediate suspension.
- 8.29 Ex parte communications.
- 8.30 Transmission of written communications by reviewing official and calculation of deadlines.
- 8.31 Authority and responsibilities of the reviewing official.
- 8.32 Administrative record.
- 8.33 Written decision.
- 8.34 Court review of final administrative action; exhaustion of administrative remedies.

AUTHORITY: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd-2, 300x-23, 300x-27(a), 300y-11.

SOURCE: 66 FR 4090, Jan. 17, 2001, unless otherwise noted.

### Subpart A—Accreditation

#### § 8.1 Scope.

The regulations in this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid addiction. These regulations also establish the Secretary's standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner

who intends to dispense opioid drugs in the treatment of opioid addiction must first obtain from the Secretary or by delegation, from the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary's standards for opiate addiction treatment with an opioid agonist treatment medication.

#### § 8.2 Definitions.

The following definitions apply to this part:

*Accreditation* means the process of review and acceptance by an accreditation body.

*Accreditation body* means a body that has been approved by SAMHSA under § 8.3 to accredit opioid treatment programs using opioid agonist treatment medications.

*Accreditation body application* means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body, as described in § 8.3(b).

*Accreditation elements* mean the elements or standards that are developed and adopted by an accreditation body and approved by SAMHSA.

*Accreditation survey* means an onsite review and evaluation of an opioid treatment program by an accreditation body for the purpose of determining compliance with the Federal opioid treatment standards described in § 8.12.

*Accredited opioid treatment program* means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA under § 8.3(d).

*Certification* means the process by which SAMHSA determines that an



opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards.

*Certification application* means the application filed by an opioid treatment program for purposes of obtaining certification from SAMHSA, as described in § 8.11(b).

*Certified opioid treatment program* means an opioid treatment program that is the subject of a current, valid certification under § 8.11.

*Comprehensive maintenance treatment* is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

*Detoxification treatment* means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period.

*Federal opioid treatment standards* means the standards established by the Secretary in § 8.12 that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment. The Federal opioid treatment standards established in § 8.12 also include the standards established by the Secretary regarding the quantities of opioid drugs which may be provided for unsupervised use.

*For-cause inspection* means an inspection of an opioid treatment program by the Secretary, or by an accreditation body, that may be operating in violation of Federal opioid treatment standards, may be providing substandard treatment, or may be serving as a possible source of diverted medications.

*Interim maintenance treatment* means maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

*Long-term detoxification treatment* means detoxification treatment for a period more than 30 days but not in excess of 180 days.

*Maintenance treatment* means the dispensing of an opioid agonist treatment medication at stable dosage levels for a

period in excess of 21 days in the treatment of an individual for opioid addiction.

*Medical director* means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

*Medical and rehabilitative services* means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), that are intended to help patients in opioid treatment programs become and/or remain productive members of society.

*Medication unit* means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

*Opiate addiction* is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

*Opioid agonist treatment medication* means any opioid agonist drug that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opiate addiction.

*Opioid drug* means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

*Opioid treatment* means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opiate addiction. This term encompasses detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

*Opioid treatment program* or “OTP” means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.

*Patient* means any individual who undergoes treatment in an opioid treatment program.

*Program sponsor* means the person named in the application for certification described in § 8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

*Registered opioid treatment program* means an opioid treatment program that is registered under 21 U.S.C. 823(g).

*Short-term detoxification treatment* means detoxification treatment for a period not in excess of 30 days.

*State Authority* is the agency designated by the Governor or other appropriate official designated by the Governor to exercise the responsibility and authority within the State or Territory for governing the treatment of opiate addiction with an opioid drug.

*Treatment plan* means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which specifies the services to be provided and the frequency and schedule for their provision.

### § 8.3 Application for approval as an accreditation body.

(a) *Eligibility.* Private nonprofit organizations or State governmental entities, or political subdivisions thereof, capable of meeting the requirements of this part may apply for approval as an accreditation body.

(b) *Application for initial approval.* Three copies of an accreditation body application form [SMA-163] shall be submitted to SAMHSA at rm. 12-105, 5600 Fishers Lane, Rockville, MD 20857, and marked ATTENTION: OTP Certification Program. SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. Accreditation body applications shall include the following information and supporting documentation:

(1) Name, address, and telephone number of the applicant and a responsible official for the accreditation body. The application shall be signed by the responsible official;

(2) Evidence of the nonprofit status of the applicant (*i.e.*, of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State governmental entity or political subdivision;

(3) A set of the accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid treatment standards set forth in § 8.12;

(4) A detailed description of the applicant's decisionmaking process, including:

(i) Procedures for initiating and performing onsite accreditation surveys of OTPs;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process, including a request for a complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation is true and accurate, and that no material fact has been omitted;

(iv) Policies and procedures for notifying OTPs and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs;

(v) Policies and procedures for suspending or revoking an OTP's accreditation;

(vi) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a time-frame approved by SAMHSA; and

(vii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions.

(5) Policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest, by the applicant's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives;

(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the applicant's staff;

(7) A description of the applicant's training policies;

(8) Fee schedules, with supporting cost data;

(9) Satisfactory assurances that the body will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);

(10) Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body; and

(11) Any other information SAMHSA may require.

(c) *Application for renewal of approval.* An accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to SAMHSA for renewal, or notify SAMHSA of its intention not to apply for renewal, in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of an accreditation body's term of approval, the body shall inform SAMHSA in writing of its intent to seek renewal.

(2) SAMHSA will notify the applicant of the relevant information, materials, and supporting documentation required under paragraph (b) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 3 months before the date of expiration of the accreditation body's term of approval, the applicant shall furnish to SAMHSA three copies of a renewal application containing the information, materials, and supporting documentation requested by SAMHSA under paragraph (c)(2) of this section.

(4) An accreditation body that does not intend to renew its approval shall so notify SAMHSA at least 9 months before the expiration of the body's term of approval.

(d) *Rulings on applications for initial approval or renewal of approval.* (1) SAMHSA will grant an application for initial approval or an application for renewal of approval if it determines the applicant substantially meets the accreditation body requirements of this subpart.

(2) If SAMHSA determines that the applicant does not substantially meet the requirements set forth in this subpart, SAMHSA will notify the applicant of the deficiencies in the application and request that the applicant resolve such deficiencies within 90 days of receipt of the notice. If the deficiencies are resolved to the satisfaction of SAMHSA within the 90-day time period, the body will be approved as an accreditation body. If the deficiencies have not been resolved to the satisfaction of SAMHSA within the 90-day time period, the application for approval as an accreditation body will be denied.

(3) If SAMHSA does not reach a final decision on a renewal application before the expiration of an accreditation body's term of approval, the approval will be deemed extended until SAMHSA reaches a final decision, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of approval.* An accreditation body that intends to relinquish its accreditation approval before

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expiration of the body's term of approval shall submit a letter of such intent to SAMHSA, at the address in paragraph (b) of this section, at least 9 months before relinquishing such approval.

(f) *Notification.* An accreditation body that does not apply for renewal of approval, or is denied such approval by SAMHSA, relinquishes its accreditation approval before expiration of its term of approval, or has its approval withdrawn, shall:

(1) Transfer copies of records and other related information as required by SAMHSA to a location, including another accreditation body, and according to a schedule approved by SAMHSA; and

(2) Notify, in a manner and time period approved by SAMHSA, all OTPs accredited or seeking accreditation by the body that the body will no longer have approval to provide accreditation services.

(g) *Term of approval.* An accreditation body's term of approval is for a period not to exceed 5 years.

(h) *State accreditation bodies.* State governmental entities, including political subdivisions thereof, may establish organizational units that may act as accreditation bodies, provided such units meet the requirements of this section, are approved by SAMHSA under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support opioid treatment services.

#### § 8.4 Accreditation body responsibilities.

(a) *Accreditation surveys and for cause inspections.* (1) Accreditation bodies shall conduct routine accreditation surveys for initial, renewal, and continued accreditation of each OTP at least every 3 years.

(2) Accreditation bodies must agree to conduct for-cause inspections upon the request of SAMHSA.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved accreditation body application.

(b) *Response to noncompliant programs.* (1) If an accreditation body receives or

discovers information that suggests that an OTP is not meeting Federal opioid treatment standards, or if survey of the OTP by the accreditation body otherwise demonstrates one or more deficiencies in the OTP, the accreditation body shall as appropriate either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies.

(i) Accreditation bodies shall either not accredit or shall revoke the accreditation of any OTP that substantially fails to meet the Federal opioid treatment standards.

(ii) Accreditation bodies shall notify SAMHSA as soon as possible but in no case longer than 48 hours after becoming aware of any practice or condition in an OTP that may pose a serious risk to public health or safety or patient care.

(iii) If an accreditation body determines that an OTP is substantially meeting the Federal opioid treatment standards, but is not meeting one or more accreditation elements, the accreditation body shall determine the necessary corrective measures to be taken by the OTP, establish a schedule for implementation of such measures, and notify the OTP in writing that it must implement such measures within the specified schedule in order to ensure continued accreditation. The accreditation body shall verify that the necessary steps are taken by the OTP within the schedule specified and that all accreditation elements are being substantially met or will be substantially met.

(2) Nothing in this part shall prevent accreditation bodies from granting accreditation, contingent on promised programmatic or performance changes, to OTPs with less substantial violations. Such accreditation shall not exceed 12 months. OTPs that have been granted such accreditation must have their accreditation revoked if they fail to make changes to receive unconditional accreditation upon resurvey or reinspection.

(c) *Recordkeeping.* (1) Accreditation bodies shall maintain records of their accreditation activities for at least 5 years from the creation of the record.

Such records must contain sufficient detail to support each accreditation decision made by the accreditation body.

(2) Accreditation bodies shall establish procedures to protect confidential information collected or received in their role as accreditation bodies that are consistent with, and that are designed to ensure compliance with, all Federal and State laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to SAMHSA or its duly designated representatives, unless otherwise required by law or with the consent of the OTP.

(ii) Nonpublic information that SAMHSA shares with the accreditation body concerning an OTP shall not be further disclosed except with the written permission of SAMHSA.

(d) *Reporting.* (1) Accreditation bodies shall provide to SAMHSA any documents and information requested by SAMHSA within 5 days of receipt of the request.

(2) Accreditation bodies shall make a summary of the results of each accreditation survey available to SAMHSA upon request. Such summaries shall contain sufficient detail to justify the accreditation action taken.

(3) Accreditation bodies shall provide SAMHSA upon request a list of each OTP surveyed and the identity of all individuals involved in the conduct and reporting of survey results.

(4) Accreditation bodies shall submit to SAMHSA the name of each OTP for which the accreditation body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to SAMHSA under paragraphs (d)(1) through (d)(4) of this section, each accreditation body shall submit to SAMHSA semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

(6) All reporting requirements listed in this section shall be provided to SAMHSA at the address specified in § 8.3(b).

(e) *Complaint response.* Accreditation bodies shall have policies and procedures to respond to complaints from SAMHSA, patients, facility staff, and others, within a reasonable period of time but not more than 5 days of the receipt of the complaint. Accreditation bodies shall also agree to notify SAMHSA within 48 hours of receipt of a complaint and keep SAMHSA informed of all aspects of the response to the complaint.

(f) *Modifications of accreditation elements.* Accreditation bodies shall obtain SAMHSA's authorization prior to making any substantive (*i.e.*, noneditorial) change in accreditation elements.

(g) *Conflicts of interest.* The accreditation body shall maintain and apply policies and procedures that SAMHSA has approved in accordance with § 8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the accreditation body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision.

(h) *Accreditation teams.* (1) An accreditation body survey team shall consist of healthcare professionals with expertise in drug abuse treatment and, in particular, opioid treatment. The accreditation body shall consider factors such as the size of the OTP, the anticipated number of problems, and the OTP's accreditation history, in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of drugs subject to control under the Controlled Substances Act (21 U.S.C. 801 *et seq.*);

(ii) Medical issues relating to the dosing and administration of opioid

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agonist treatment medications for the treatment of opioid addiction;

(iii) Psychosocial counseling of individuals undergoing opioid treatment; and

(iv) Organizational and administrative issues associated with opioid treatment programs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest.

(i) *Accreditation fees.* Fees charged to OTPs for accreditation shall be reasonable. SAMHSA generally will find fees to be reasonable if the fees are limited to recovering costs to the accreditation body, including overhead incurred. Accreditation body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At SAMHSA's request, accreditation bodies shall provide to SAMHSA financial records or other materials, in a manner specified by SAMHSA, to assist in assessing the reasonableness of accreditation body fees.

## § 8.5 Periodic evaluation of accreditation bodies.

SAMHSA will evaluate periodically the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the Federal opioid treatment standards. The evaluation will include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under § 8.6.

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## § 8.6 Withdrawal of approval of accreditation bodies.

If SAMHSA determines that an accreditation body is not in substantial compliance with this subpart, SAMHSA shall take appropriate action as follows:

(a) *Major deficiencies.* If SAMHSA determines that the accreditation body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, SAMHSA shall withdraw approval of that accreditation body.

(1) In the event of a major deficiency, SAMHSA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the accreditation body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by SAMHSA.

(b) *Minor deficiencies.* If SAMHSA determines that the accreditation body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, SAMHSA will notify the body that it has 90 days to submit to SAMHSA a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. SAMHSA may place the body on probationary status for a period of time determined by SAMHSA, or may withdraw approval of the body if corrective action is not taken.

(1) If SAMHSA places an accreditation body on probationary status, the body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the accreditation body's probationary status within a time period and in a manner approved by SAMHSA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of

SAMHSA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If SAMHSA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, SAMHSA may withdraw approval of the accreditation body. The accreditation body shall notify all OTPs that have been accredited, or are seeking accreditation, of the accreditation body's loss of SAMHSA approval within a time period and in a manner approved by SAMHSA.

(c) *Reapplication.* (1) An accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to SAMHSA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If SAMHSA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, SAMHSA may reinstate approval of the accreditation body.

(3) SAMHSA may request additional information or establish additional conditions that must be met before SAMHSA approves the reapplication.

(4) SAMHSA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) *Hearings.* An opportunity to challenge an adverse action taken regarding withdrawal of approval of an accreditation body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in § 8.28 for expedited review of an immediate suspension would not apply to an accreditation body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.

## Subpart B—Certification and Treatment Standards

### § 8.11 Opioid treatment program certification.

(a) *General.* (1) An OTP must be the subject of a current, valid certification from SAMHSA to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) to dispense opioid drugs in the treatment of opioid addiction. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense opioid agonist treatment medications to individuals for treatment of opioid addiction.

(2) To obtain certification from SAMHSA, an OTP must meet the Federal opioid treatment standards in § 8.12, must be the subject of a current, valid accreditation by an accreditation body or other entity designated by SAMHSA, and must comply with any other conditions for certification established by SAMHSA.

(3) Certification shall be granted for a term not to exceed 3 years, except that certification may be extended during the third year if an application for accreditation is pending.

(b) *Application for certification.* Three copies of an application for certification must be submitted by the OTP to the address identified in § 8.3(b). SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. The application for certification shall include:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the control of the OTP;

(5) The sources of funding for the OTP and the name and address of each governmental entity that provides such funding; and

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (f) of this section.

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(c) *Action on application.* (1) Following SAMHSA's receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, SAMHSA may grant the application for certification, or renew an existing certification, if SAMHSA determines that the OTP has satisfied the requirements for certification or renewal of certification.

(2) SAMHSA may deny the application if SAMHSA determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the Federal opioid treatment standards established under § 8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification, SAMHSA will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide opioid treatment under section 303(g)(1) of the Controlled Substances Act.

(d) *Transitional certification.* OTPs that before May 18, 2001 were the subject of a current, valid approval by FDA under 21 CFR, part 291 (contained in the 21 CFR parts 200 to 299 edition, revised as of July 1, 2000), are deemed to be the subject of a current valid certification for purposes of paragraph (a)(11) of this section. Such "transitional certification" will expire on August 17, 2001 unless the OTP submits the information required by paragraph (b) of this section to SAMHSA on or before August 17, 2001. In addition to this application, OTPs must certify with a written statement signed by the pro-

gram sponsor, that they will apply for accreditation within 90 days of the date SAMHSA approves the second accreditation body. Transitional certification, in that case, will expire on May 19, 2003. SAMHSA may extend the transitional certification of an OTP for up to one additional year provided the OTP demonstrates that it has applied for accreditation, that an accreditation survey has taken place or is scheduled to take place, and that an accreditation decision is expected within a reasonable period of time (e.g., within 90 days from the date of survey). Transitional certification under this section may be suspended or revoked in accordance with § 8.14.

(e) *Provisional certification.* (1) OTPs that have no current certification from SAMHSA, but have applied for accreditation with an accreditation body, are eligible to receive a provisional certification for up to 1 year. To receive a provisional certification, an OTP shall submit the information required by paragraph (b) of this section to SAMHSA along with a statement identifying the accreditation body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. A provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph, unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification.

(2) An extension of provisional certification may be granted in extraordinary circumstances or otherwise to protect public health. To apply for a 90-day extension of provisional certification, an OTP shall submit to SAMHSA a statement explaining its efforts to obtain accreditation and a schedule for obtaining accreditation as expeditiously as possible.

(f) *Conditions for certification.* (1) OTPs shall comply with all pertinent State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use



of opioid drugs in the treatment of opioid addiction. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States. Federal agencies operating OTPs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal OTPs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, by the DEA, and by authorized employees of any relevant State or Federal governmental authority.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2, and every program must comply with that part. Records on the receipt, storage, and distribution of opioid agonist treatment medications are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*). Federally-sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of SAMHSA to have access to and to copy all records on the use of opioid drugs in accordance with the provisions of 42 CFR part 2.

(5) OTPs shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II, and must be registered by the DEA before administering or

dispensing opioid agonist treatment medications.

(7) OTPs must operate in accordance with Federal opioid treatment standards and approved accreditation elements.

(g) *Conditions for interim maintenance treatment program approval.* (1) Before a public or nonprofit private OTP may provide interim maintenance treatment, the program must receive the approval of both SAMHSA and the chief public health officer of the State in which the OTP operates.

(2) Before SAMHSA may grant such approval, the OTP must provide SAMHSA with documentation from the chief public health officer of the State in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim maintenance treatment in the State;

(ii) The OTP seeking to provide such treatment is unable to place patients in a public or nonprofit private comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek admission to such programs;

(iii) The authorization of the OTP to provide interim maintenance treatment will not otherwise reduce the capacity of comprehensive maintenance treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and

(iv) The State certifies that each individual enrolled in interim maintenance treatment will be transferred to a comprehensive maintenance treatment program no later than 120 days from the date on which each individual first requested treatment, as provided in section 1923 of the Public Health Service Act (21 U.S.C. 300x-23).

(3) SAMHSA will provide notice to the OTP denying or approving the request to provide interim maintenance treatment. The OTP shall not provide such treatment until it has received such notice from SAMHSA.

(h) *Exemptions.* An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be

granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

(i) *Medication units, long-term care facilities and hospitals.* (1) Certified OTPs may establish medication units that are authorized to dispense opioid agonist treatment medications for observed ingestion. Before establishing a medication unit, a certified OTP must notify SAMHSA by submitting form SMA-162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent state laws and regulations.

(2) Certification as an OTP under this part will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility. The terms “hospital” and “long-term care facility” as used in this section are to have the meaning that is assigned under the law of the State in which the treatment is being provided. Nothing in this section is intended to relieve hospitals and long-term care facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

[66 FR 4090, Jan. 17, 2001, as amended at 66 FR 15347, Mar. 19, 2001]

#### § 8.12 Federal opioid treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current “Diversion Control Plan” or “DCP” as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials.* Each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply

with the credentialing requirements of their respective professions.

(e) *Patient admission criteria*—(1) *Maintenance treatment*. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) *Maintenance treatment for persons under age 18*. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) *Maintenance treatment admission exceptions*. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) *Detoxification treatment*. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be

assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) *Required services*—(1) *General*. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) *Initial medical examination services*. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) *Special services for pregnant patients*. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) *Initial and periodic assessment services*. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which

these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) *Counseling services.* (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) *Drug abuse testing services.* OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) *Recordkeeping and patient confidentiality.* (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in

accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of

opioid addiction. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

- (i) Methadone;
- (ii) Levomethadyl acetate (LAAM); and
- (iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid addiction.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) *Unsupervised or "take-home" use.* To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, e.g., drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is three doses per week.

(iv) In the remaining months of the first year, a patient may be given a

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maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91–601 (15 U.S.C. 1471 *et seq.*)).

(j) *Interim maintenance treatment.* (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws,

including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or “take-home” use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

[66 FR 4090, Jan. 17, 2001, as amended at 68 FR 27939, May 22, 2003]

### § 8.13 Revocation of accreditation and accreditation body approval.

(a) *SAMHSA action following revocation of accreditation.* If an accreditation body revokes an OTP's accreditation, SAMHSA may conduct an investigation into the reasons for the revocation. Following such investigation, SAMHSA may determine that the OTP's certification should no longer be in effect, at which time SAMHSA will initiate procedures to revoke the facility's certification in accordance with

§ 8.14. Alternatively, SAMHSA may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation body approval.* (1) If SAMHSA withdraws the approval of an accreditation body under § 8.6, the certifications of OTPs accredited by such body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the accreditation body, unless SAMHSA determines that to protect public health or safety, or because the accreditation body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. SAMHSA may extend the time in which a certification remains in effect under this paragraph on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by SAMHSA, OTPs currently accredited by the accreditation body must obtain accreditation from another accreditation body. SAMHSA may extend the time period for obtaining reaccreditation on a case-by-case basis.

#### § 8.14 Suspension or revocation of certification.

(a) *Revocation.* Except as provided in paragraph (b) of this section, SAMHSA may revoke the certification of an OTP if SAMHSA finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with subpart C of this part, that the program sponsor, or any employee of the OTP:

(1) Has been found guilty of misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal opioid treatment standards in any respect;

(3) Has failed to comply with reasonable requests from SAMHSA or from an accreditation body for records, information, reports, or materials that are

necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal opioid treatment standards; or

(4) Has refused a reasonable request of a duly designated SAMHSA inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or accreditation body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever SAMHSA has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, SAMHSA may immediately suspend the certification of an OTP before holding a hearing under subpart C of this part. SAMHSA may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under subpart C of this part if SAMHSA makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal opioid treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal opioid treatment standards was intentional or was associated with fraud.

(c) *Written notification.* In the event that SAMHSA suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, SAMHSA shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action and shall state that the OTP may seek review of the action in accordance with the procedures in subpart C of this part.

(d)(1) If SAMHSA suspends certification in accordance with paragraph (b) of this section:

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(i) SAMHSA will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) SAMHSA will provide an opportunity for a hearing under subpart C of this part.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

### § 8.15 Forms.

(a) SMA-162—Application for Certification to Use Opioid Agonist Treatment Medications for Opioid Treatment.

(b) SMA-163—Application for Becoming an Accreditation Body under § 8.3.

## Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

### § 8.21 Applicability.

The procedures in this subpart apply when:

(a) SAMHSA has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that SAMHSA proposes to revoke the certification; and

(b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing an opportunity for a review of the suspension or proposed revocation.

(c) SAMHSA has notified an accreditation body of an adverse action taken regarding withdrawal of approval of the accreditation body under the regulations in subpart A of this part; and

(d) The accreditation body has, within 30 days of the date of the notification,

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requested in writing an opportunity for a review of the adverse action.

### § 8.22 Definitions.

The following definitions apply to this subpart C.

(a) *Appellant* means:

(1) The treatment program which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation, or

(2) The accreditation body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.

(b) *Respondent* means SAMHSA.

(c) *Reviewing official* means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more HHS officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

### § 8.23 Limitation on issues subject to review.

The scope of review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts the regulations, in the subpart, and other relevant law.

### § 8.24 Specifying who represents the parties.

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

### § 8.25 Informal review and the reviewing official's response.

(a) *Request for review.* Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to



the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension, proposed revocation, or adverse action, a brief statement of why the decision to suspend, propose revocation, or take an adverse action is incorrect, and the appellant's request for an oral presentation, if desired.

(b) *Acknowledgment.* Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

#### § 8.26 Preparation of the review file and written arguments.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's documents and brief.* Within 30 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification or to take adverse action regarding withdrawal of approval of the accreditation body is incorrect (appellant's brief).

(b) *Respondent's documents and brief.* Within 30 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification, or approval as an accredita-

tion body, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension, proposed revocation, or adverse action (respondent's brief).

(c) *Reply briefs.* Within 10 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive documentation.* The reviewing official may take any appropriate steps to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

(f) *Discovery.* The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

#### § 8.27 Opportunity for oral presentation.

(a) *Electing oral presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decisionmaking process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing;

time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and place of oral presentation.* The presiding official will attempt to schedule the oral presentation within 45 days of the date appellant's request for review is received or within 15 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the oral presentation—*  
(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more HHS officers or employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of proof/standard of proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend, propose revocation, or take adverse action is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) *Admission of evidence.* The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the pre-hearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation

only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of justice or making of false statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1001 or 1505.

(g) *Post-hearing procedures.* At the presiding official's discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

#### **§ 8.28 Expedited procedures for review of immediate suspension.**

(a) *Applicability.* When the Secretary notifies a treatment program in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 10 days of the date the OTP received notice of the suspension. The request for review must include a

copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing official's response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review file and briefs.* Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with § 8.27(a), the presiding official will attempt to schedule the oral presentation within 20 to 30 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with § 8.27(c) and will conduct the oral presentation in accordance with the procedures of §§ 8.27(e), (f), and (g).

(e) *Written decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in § 8.33 apply.

(f) *Transmission of written communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either

party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.

#### **§ 8.29 Ex parte communications.**

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

#### **§ 8.30 Transmission of written communications by reviewing official and calculation of deadlines.**

(a) *Timely review.* Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, or commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) *Due date.* In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

#### **§ 8.31 Authority and responsibilities of the reviewing official.**

In addition to any other authority specified in this subpart C, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary

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to resolve disputes in accordance with the objectives of the procedures in this subpart.

#### § 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

#### § 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the FEDERAL REGISTER. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the FEDERAL REGISTER. SAMHSA will notify DEA

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within 5 days that the OTP's registration should be restored, if applicable.

#### § 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

## PART 9—STANDARDS OF CARE FOR CHIMPANZEES HELD IN THE FEDERALLY SUPPORTED SANCTUARY SYSTEM

### Sec.

- 9.1 Applicability and purpose.
- 9.2 Definitions.
- 9.3 Sanctuary policies and responsibilities.
- 9.4 Physical facility policies and design.
- 9.5 Chimpanzee ownership, fees, and studies.
- 9.6 Animal care, well-being, husbandry, veterinary care, and euthanasia.
- 9.7 Reproduction.
- 9.8 Animal records.
- 9.9 Facility staffing.
- 9.10 Occupational Health and Safety Program (OHSP) and biosafety requirements.
- 9.11 Animal transport.
- 9.12 Compliance with the Standards of Care, and USDA and PHS policies and regulations.
- 9.13 Other federal laws, regulations, and statutes that apply to this part.

AUTHORITY: 42 U.S.C. 216, 287a–3a.

SOURCE: 73 FR 60423, Oct. 10, 2008, unless otherwise noted.

#### § 9.1 Applicability and purpose.

(a) *General.* The standards of care set forth in this part apply to the chimpanzee sanctuaries that are contracted (or subcontracted) to the Federal Government to operate the federally supported chimpanzee sanctuary system authorized by section 481C of the Public Health Service (PHS) Act, as amended (42 U.S.C. 287a–3a).

(b) *What is the purpose of the federally supported chimpanzee sanctuary system and the authority for establishing these*

*standards of care regulation?* The Chimpanzee Health Improvement, Maintenance, and Protection Act (Pub. L. 106-551, referred to as the “CHIMP Act” or “Chimpanzee Retirement Act”) was enacted by Congress to provide for the establishment and operation of a sanctuary system to provide lifetime care for chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the agencies of the Federal Government, and that are determined to be no longer needed for such research. The CHIMP Act also mandates that standards of care for chimpanzees in the sanctuary shall be developed to ensure the well-being of chimpanzees and the health and safety of the chimpanzees.

(c) *To what chimpanzee sanctuaries do the standards of care in this part apply?* The standards of care set forth in this part apply to only those sanctuaries that are contracted or subcontracted to the Federal Government to operate the federally supported chimpanzee sanctuary system.

## §9.2 Definitions.

As used in this part:

*Adequate veterinary care* means a program directed by a veterinarian qualified through training and/or experience to provide professional medical care to the chimpanzees within the Sanctuary and with the appropriate authority to provide this care. The program also provides guidance to all caregivers on all matters relating to the health and well-being of the chimpanzees.

*American Zoo and Aquarium Association (AZA)* means the professional society composed of individuals with various backgrounds and interests that are devoted to advancing the knowledge and understanding of zoo animals and the management of zoos in the United States.

*American Zoo and Aquarium Association (AZA) Accreditation Standards* are those standards developed by the AZA that are used to review, evaluate, and accredit zoos or zoological gardens. These standards cover a variety of areas including facilities, policies and procedures, training, staff qualifications, medical and animal care, husbandry and well-being procedures, and

conservation, along with other specific areas.

*Animal Care and Use Committee* means the Institutional Animal Care and Use Committee established under section 13(b) of the Animal Welfare Act of 1985 and the Health Research Extension Act of 1985. For the purpose of these Standards of Care, it shall consist of at least five (5) members including the Chairperson, a Doctor of Veterinary Medicine (D.V.M. or V.M.D.) knowledgeable in nonhuman primate care and diseases and with delegated program responsibility, a member not affiliated with the Sanctuary, a scientist, and a member of the animal protection community. The requirement that a member of the ACUC must be from an animal protection organization is unique to this part and is not required under the Animal Welfare Regulations or the Public Health Service Policy on the Humane Care and Use of Laboratory Animals. This Committee must be established if research as defined by the Animal Welfare Act Regulations and the Public Health Service Policy (research, teaching, testing, exhibition) is to be conducted at the sanctuary.

*Animal protection organization* means a nonprofit organization whose primary mission is protection of animals through positive advocacy and action.

*Animal Resource Manager (or Animal Resource Supervisor)* means the individual employee responsible for managing the nonprofessional staff providing care for the chimpanzees at the sanctuary. This individual may perform other duties as assigned by the Sanctuary Contractor.

*Animal Welfare Act/Regulations* means the Act of August 24, 1966 (Pub. L. 89-544, commonly known as the Laboratory Animal Welfare Act), as amended by the Act of December 24, 1970 (Pub. L. 91-579, the Animal Welfare Act of 1970), the Act of April 22, 1976 (Pub. L. 94-279, the Animal Welfare Act of 1976), and the Act of December 23, 1985 (Pub. L. 99-198, the Food Security Act of 1985), and as may be subsequently amended, and the United States Department of Agriculture (USDA) regulations implementing the Animal Welfare Act in title 9, chapter 1, subchapter A of the CFR.

*Animal Welfare Assurance* means the documentation from an institution assuring compliance with the PHS Policy on Humane Care and Use of Laboratory Animals. This policy is administered by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health.

*Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC)* means the nonprofit organization that is recognized in the United States and abroad as being the body responsible for the accreditation of laboratory animal programs.

*Behaviorist* means a person hired by the sanctuary to administer or oversee the enrichment and behavioral program for the chimpanzees at the sanctuary. This individual must be qualified through training or experience.

*Biosafety Officer* means the individual responsible for establishing and monitoring workplace safety procedures designed to minimize or prevent injury or loss due to biohazards in accordance with policies established by the sanctuary administration.

*Board of Directors (BOD)* means the individuals selected by the Contractor to govern the nonprofit institution responsible for operating the federally supported chimpanzee Sanctuary system. The board members must meet the qualifications and criteria stated in the CHIMP Act.

*Chair of the Board of Directors* means the individual chosen by the BOD or other legally empowered entity to carry out such action, who is responsible for chairing meetings and acting on behalf of the board. This individual reports directly to the Board.

*Chief Executive Officer (CEO)* means the principal person responsible for overall accomplishment of the mission of the chimpanzee sanctuary.

*CHIMP Act* means the Chimpanzee Health Improvement, Maintenance, and Protection Act of December 20, 2000 (Pub. L. 106–551) commonly known as the “CHIMP Act” or “Chimpanzee Retirement Act,” and any future amendments.

*Chimpanzee* means a member of *Pan troglodytes*. It excludes the pygmy chimpanzee (*Pan paniscus* or bonobo).

*Chimpanzee caregivers (caregivers)* mean all sanctuary technical and hus-

bandry staff providing long-term care and services for the chimpanzees.

*Contractor/Primary Contractor/Sanctuary Contractor* means the nonprofit entity awarded a contract by the Federal Government to establish and operate the chimpanzee sanctuary system.

*Euthanasia* means the humane death of a chimpanzee accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress. The method must be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia.

*Exhibition* means exhibiting chimpanzees to the public for compensation. This definition excludes limited viewing for educational purposes that are not disruptive to the chimpanzees.

*Facility director* means the individual responsible for directing the overall activities at the Sanctuary site.

*Facility Veterinarian* means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association (AVMA) Council on Education, or who has a certificate issued by the AVMA’s Education Commission for Foreign Veterinary Graduates; has training and/or experience in the care and management of nonhuman primates; and has direct or delegated authority for activities involving chimpanzees at the federally funded chimpanzee sanctuary.

*Federal Acquisition Regulations (FAR)* means the codified rules applicable to contracts, specifically those sections of the FAR (48 CFR chapter 1, part 52) that are applicable to contracts between the Federal Government and a contractor (in this case a private, nonprofit entity under contract to operate the chimpanzee sanctuary system).

*Federal agency* means an executive agency as such term is defined in section 105 of title 5, United States Code, and refers to the agency from which the research facility receives a Federal award for projects involving animals.

*Federally owned chimpanzees* mean chimpanzees that have been purchased by, bred by, or donated to a federal agency for use in biomedical/behavioral research. Chimpanzees whose ownership was subsequently transferred from Federal ownership via written transfer

agreements are no longer federally owned.

*Guide* means *The Guide for the Care and Use of Laboratory Animals*, published by the National Academy of Sciences, Institute for Laboratory Animal Research of the National Research Council, 1996, International Standard Book Number 0-309-05377-3.

*Housing facility* means any land, premises, shed, barn, building, trailer, or other structure or area housing intended to house chimpanzees.

*Indoor housing facility* refers to any structure or enclosure (for example, cages, pens, rooms) for maintaining animals in a controlled environment that provides for normal physiological and behavioral needs.

*Interstate air transport live animals (IATA) regulations* means those regulations and standards covering the air transportation of nonhuman primates developed and implemented by the International Air Transportation Association.

*Invasive research (studies)* utilizes those procedures that cause more than momentary pain, distress, fear, discomfort, injury, or other negative modalities to a chimpanzee. Any procedure that enters or exposes a body cavity is considered to be invasive. Sanctuary chimpanzees may not be used in invasive research. This definition excludes any invasive procedure that is a part of veterinary, medical, or surgical care that is performed by or under the direction of the Sanctuary Veterinarian using acceptable veterinary practices. Some examples of invasive studies are:

(1) Experimental exposure to a substance that may be detrimental to a chimpanzee's health (e.g., infectious disease, radiation). This does not include accidental exposures to infectious diseases transmitted from cage mates or from radiation or other exposures at the time of regularly scheduled or necessary veterinary examinations and treatments;

(2) Any invasion of a body cavity;

(3) Surgery and surgical implantation of devices that are not a part of a veterinary medical treatment or colony management purposes.

(4) Behavioral studies that cause distress or discomfort, such as induction of a fear response;

(5) Testing of any drug;

(6) Purposeful manipulation of social groups or the removal from their social group or addition of individuals in order to conduct behavioral research (for example, on aggression). Creation and refinement of social groups will be necessary when the animals arrive at the Sanctuary and this should take place only when necessary in regards to colony management and should not be driven by independently initiated research studies;

(7) Restraint unless it is in conjunction with the annual exam or clinical care; and

(8) Darting or anesthesia induction other than at annual exam or in the case of an emergency in which the chimpanzee's well-being is at stake.

*National Primate Research Center (NPRC)* means those centers supported by the National Center for Research Resources, National Institutes of Health, Department of Health and Human Services, as national resources for providing high-quality nonhuman primate research resources and facilities. As of June 2007, there were eight such centers.

*National Research Council* means the component of the National Academy of Sciences that advises the Federal Government on matters related to science, research, and research resources.

*Nonfederally owned chimpanzees* mean chimpanzees that have not been purchased by, bred by, or donated to the Federal Government for use in federally supported research projects. In accordance with the CHIMP Act, chimpanzees owned on the date of passage of the CHIMP Act by a National Primate Research Center may enter the sanctuary system without requiring the NPRC to pay a fee. Offspring born in the sanctuary is owned by the Sanctuary Contractor.

*Noninvasive research (studies)* means the use of procedures that depend upon close observation of chimpanzee behavior or on medical information collected during the course of normal veterinary care. These procedures do not require removal of the chimpanzees from their social group or environment, or require

a separate anesthetic or sedation event to collect data or record observations. Some examples of noninvasive studies are:

- (1) Visual observation;
- (2) Behavioral studies designed to improve the establishment and maintenance of social groups. These activities may cause stress as a result of novel interactions between chimpanzees and caregivers, but they are not considered invasive as long as they are intended to maximize the well-being of the chimpanzees;
- (3) Medical examinations as deemed necessary to oversee the health of the chimpanzees, in the least invasive manner possible. Collection of samples routinely obtained during a physical examination for processing during this time is also considered noninvasive since a separate event is not required;
- (4) Administration and evaluation of environmental enrichment used to promote the psychological well-being of the chimpanzees; and
- (5) Actions taken to provide essential medical treatment to an individual chimpanzee exhibiting symptoms of illness. This applies only to serious illness that cannot be treated while the chimpanzee remains within the colony.

*Outdoor housing facility (area)* means corrals, Primadomes (a prefabricated outdoor housing unit), fenced open areas, or similar structures or areas for maintaining chimpanzees with access to adequate protection from the extremes of environmental elements and harsh weather conditions.

*Outdoor ranging area* means an area that allows chimpanzees greater ranging space than corrals or other outdoor housing area and includes a variety of vegetation, shrubbery, grasses and trees, thereby providing for a fairly unrestricted natural setting for the chimpanzees to engage in species-appropriate activities. The area is secured by an outer perimeter barrier.

*Project Officer* means the individual designated by the Federal Government to represent the contracting officer and interests of the federal agency, within defined areas, in monitoring and overseeing the chimpanzee sanctuary system contract.

*Sanctuary Chimpanzee Care Committee (SCCC) or similar designated committee*

means the group of individuals designated by the CEO of the sanctuary that reviews and monitors adherence to the policies, procedures, and regulations at the sanctuary.

*Sanctuary Contractor* means the non-profit, private entities selected by NCRR/NIH to develop and operate the chimpanzee sanctuary system. This contractor is also known as the “primary contractor” for the sanctuary system.

*Sanctuary Director* means the individual who provides day-to-day direction and oversight to the employees responsible for performing the daily tasks at the facility.

*Sanctuary or federally supported chimpanzee sanctuary system* means the sanctuary or sanctuary system established by the Federal Government through contracting with a private, nonprofit entity, for the purpose of carrying out the provisions of the CHIMP Act of 2000. The system includes a primary Contractor and may include additional subcontractors as required. This sanctuary system is supported primarily from funds allocated by NCRR/NIH/HHS with some matching funds from the nonprofit contractor.

*Secretary* means the Secretary of Health and Human Services or his/her designee.

*Subcontractor* means a private, non-profit entity selected by the primary contractor to provide additional sanctuary services.

*Surplus chimpanzees* means chimpanzees that are no longer needed in research and that were used, or were bred or purchased for use, in research conducted or supported by the Federal Government.

*USDA licensed intermediate handler/carrier* means any person, including a department, agency, or instrumentality of the United States or of any State or local government, who is engaged in any business in which it receives custody of animals in connection with their transportation in commerce and who is licensed by the USDA.

*Zoonotic disease(s)* means diseases that are transmissible from chimpanzees to humans.



**§ 9.3 Sanctuary policies and responsibilities.**

(a) *What are the policies and responsibilities governing the sanctuary system?* It will be the policies and responsibilities of the sanctuary system to:

(1) Appoint a Board of Directors (BOD) responsible for the overall governance and direction of the Sanctuary. The BOD shall designate the Chief Executive Officer (CEO), who is responsible for the management and oversight of the daily operations of the sanctuary and the performance of other delegated tasks. Subcontractors, if applicable, shall be governed by the policies that are developed by the Board of Directors of the primary contractor.

(2) Direct the BOD to:

(i) Ensure that chimpanzees accepted into the sanctuary are not discharged;

(ii) Develop guidelines for accepting chimpanzees not owned by the Federal Government into the sanctuary if the conditions are met as outlined in 42 U.S.C. 287;

(iii) Ensure that the Board of Directors of the primary contractor consists of no more than thirteen (13) individuals, and that the conditions governing the terms of the Board members are in compliance with the CHIMP Act;

(iv) Include individuals with the following expertise and experience as set forth in the CHIMP Act;

(A) At least one veterinarian who is qualified in veterinary care of nonhuman primates. These qualifications may be met through postdoctoral training, experience, or both;

(B) Individual(s) with expertise and experience in zoological science and with knowledge in behavioral primatology;

(C) Individual(s) with experience in the animal protection field;

(D) Individual(s) with experience and expertise in the field of business and management of nonprofit organizations;

(E) Individual(s) knowledgeable and experienced in accrediting programs of animal care;

(F) Individual(s) with experience and expertise in containing biohazards;

(v) Ensure that a member of the Board of Directors serves as the Chair of the Board of Directors, who may be

elected or appointed by the Board from among the individuals identified in paragraphs (a) (1) (iv) (A) through (F) of this section;

(vi) Ensure that no member of the board shall have been fined for, or signed a consent decree for, any violation of the Animal Welfare Act;

(vii) Create a safe and species-appropriate physical and social environment for the lifetime care of chimpanzees;

(viii) Comply with all applicable provisions of the animal welfare regulations and other federal, state and local laws, regulations, and policies;

(ix) Achieve accreditations from appropriate accrediting bodies within a reasonable time frame mutually agreed upon by the Contractor and NCRR;

(x) Prohibit any invasive research on the resident chimpanzees, but permit noninvasive studies (Definitions for the terms *invasive* and *non-invasive* are set forth in § 9.2 of this part.);

(xi) Prohibit exhibition of chimpanzees in the sanctuary (This policy does not prohibit educational activities that may involve limited viewing of chimpanzees in their environment and that are designed to promote an understanding of chimpanzee behavior, well-being, or importance to the ecological system that does not adversely affect the chimpanzees' routine.);

(xii) Staff the organization with people with appropriate experience; and

(xiii) Authorize the establishment of a Sanctuary Chimpanzee Care Committee (SCCC) that is appointed by and reports to the CEO or President of the company or corporation. The SCCC is responsible for overseeing the chimpanzee care program and operations to ensure the health and well-being of the chimpanzees and the occupational safety of the staff are being addressed. The Committee must consist of no fewer than five people who must include:

(A) A chair (person) knowledgeable of the needs of chimpanzees;

(B) A veterinarian with chimpanzee care experience;

(C) A behaviorist with experience in chimpanzee behavior;

(D) A member of the chimpanzee care staff; and

(E) Member or members from the community, including at least one with

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affiliation or employment with an animal protection organization as defined in §9.2 of this part.

(F) The SCCC will:

(1) Oversee and evaluate the chimpanzee care and socialization program;

(2) Review and approve proposed education programs. No program should be approved that might interfere with the chimpanzees' well-being or routine activities;

(3) Conduct a formal review of the program on a semiannual basis and submit reports to the Sanctuary Director. The reports must be available for review by the USDA and NIH representatives during site visits;

(4) Establish a mechanism for receipt and review of concerns involving the care of chimpanzees and resolving such concerns;

(5) Review all noninvasive study proposals. The SCCC membership may require additional qualified individuals to perform the functions of an Animal Care and Use Committee (ACUC) if and when the need arises. The contractor may establish a separate ACUC. The ACUC must be established in accordance with the applicable provisions of the Animal Welfare Act regulations, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and these standards of care;

(6) Review all euthanasia events. Euthanasia events performed for medical or humane reasons must be based upon sound professional veterinary judgment that conforms to current veterinary medical practices and must be in the best interest of the chimpanzee. Euthanasia performed for emergency reasons without advance review by the SCCC shall be reviewed by the SCCC as soon as possible after the event to ensure compliance with established policy;

(7) Establish procedures to prevent any reproduction in the colony through appropriate permanent birth control, preferably by vasectomy of all sexually mature male chimpanzees in the sanctuary; and

(8) Develop procedures for maintaining chimpanzees that are seropositive for or harboring infectious agents or previously have been exposed to infectious agents (whether experimentally induced or naturally occurring) that

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will allow them to be accepted by the sanctuary and properly housed. The procedures must be submitted to NCCRR/NIH for approval.

(b) *Who is responsible for developing or revising sanctuary policies?* (1) The Sanctuary Contractor is responsible for developing, revising, and implementing policies affecting the sanctuary.

(2) The federal agency (NCCRR/NIH) designated by the Secretary must concur with any changes that substantially change existing policies. The Secretary, or designee, will determine if a policy change will have a substantial impact upon current policy after consultation with the Sanctuary Contractor.

### §9.4 Physical facility policies and design.

(a) *What standards apply to the facility design and physical plant?* The chimpanzee sanctuary facility must be designed to provide sufficient space and variety of natural or artificial objects to accommodate natural activities of chimpanzees while restricting their movement and range to the defined area. Daily observation of chimpanzees within the enclosures is required and shall be accomplished with minimal disturbance to the chimpanzees. The facility design and physical plant should be in accordance with the recommendation of *The Guide for the Care and Use of Laboratory Animals (Guide)*, where applicable. The *Guide* is published by the National Research Council, 1996, International Standard Book Number 0-309-05377-3. The *Guide* is incorporated by reference in this section. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the publication from the National Academy Press, 2101 Constitution Avenue, NW., Lockbox 285, Washington, DC 20055; or you may order it electronically via the Internet at <http://www.nap.edu>; or view it online at <http://oacu.od.nih.gov/regs/guide/guidex.htm>.

You may inspect a copy at NIH, NCCRR, 1 Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20817-4874, or at the National Archives and Records

Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) The facility design and physical plant consist of the following components: Indoor design features; outdoor design features; construction and construction materials; physical barriers; shelter; service support space, including storage areas for food, supplies, and equipment; personnel and administrative support space; quarantine and isolation facilities; treatment area; heating, ventilation, and air conditioning (HVAC); food preparation area; and animal waste treatment.

(2) A housing system shall include indoor and outdoor enclosures that must be kept in good repair to prevent escape and injury to the chimpanzees, promote physical comfort, facilitate sanitation and servicing, and address the psychological well-being and social needs of the chimpanzees. Chimpanzees must be able to retreat from areas where they feel threatened or agitated by close human encounters or encounters with other chimpanzees.

(3) Indoor areas shall have special areas for social introductions and medical treatment. Quarantine and isolation facilities are required for the sanctuary. These facilities must be designed to prevent the spread of undesirable agents from quarantine and isolation rooms to other parts of the facility.

(4) Outdoor areas must provide sufficient ranging space and either natural or artificial structures that chimpanzees can use for shelter or nesting areas to sleep, rest, or seek refuge from rain, direct sun, wind, and extreme temperatures.

(5) Animal waste from the Sanctuary must be properly treated to remove known hazardous agents before discharging it into the environment in accordance with currently acceptable and effective waste treatment procedures, including current industry standards and Federal laws, regulations or guidelines, as applicable.

(6) An area for treatment of and performing veterinary clinical procedures on chimpanzees must be provided at

each Sanctuary site. This area must be constructed and provisioned to perform emergency procedures, including minor surgery and emergency surgical procedures, complete physical examinations, and facilities for extended care of medical conditions as needed.

(b) *What security measures are required for the sanctuary?* The sanctuary must provide adequate security against unauthorized entry, sabotage, malicious damage, and theft of chimpanzees and property and must minimize any chance of escape by a chimpanzee. The security staff must have training and/or experience in methods and equipment designed to detect possible security breaches and the ability to respond to security events in a timely and effective manner. Perimeter containment shall be used to protect the compound housing the chimpanzees consistent with the recommendations of the *Guide* (incorporated by reference, see paragraph (a) of this section).

(c) *Is the sanctuary required to develop disaster and escaped animal contingency plans?* The sanctuary facility must prepare disaster and escaped animal contingency plans outlining simple and easy to follow plans for dealing with natural and man-made disasters and steps to be taken in case a chimpanzee escapes from the compound. The Sanctuary also must provide adequate security against unauthorized entry, sabotage, malicious damage, and theft of chimpanzees and property and must minimize any chance of escape by a chimpanzee. Primary barriers must be constructed to prevent escape of chimpanzees and secondary or perimeter barriers must prevent entry of unauthorized persons into the facility, consistent with the recommendations of the *Guide* (incorporated by reference, see paragraph (a) of this section).

#### **§ 9.5 Chimpanzee ownership, fees, and studies.**

(a) *Who owns the chimpanzees in the federally supported sanctuary?* The Federal Government retains ownership of chimpanzees owned by the Federal Government at the time they enter the sanctuary system. Non-federally owned or supported chimpanzees will be

owned by the sanctuary. The chimpanzees shall continue to be maintained in the sanctuary throughout their lifetime and shall not be discharged from the sanctuary except as specifically indicated in the CHIMP Act.

(b) *Is there a charge for placing chimpanzees in the sanctuary?* No fees shall be charged by the Sanctuary Contractor for federally owned or supported chimpanzees entering the sanctuary. Chimpanzees that were owned by a NPRC when the CHIMP Act became effective are also admitted without payment of fees. Fees for maintenance of the chimpanzees alluded to above are provided for in the contract between the Federal Government and the Sanctuary Contractor.

(c) *May the sanctuary agree to accept chimpanzees that are not owned by the Federal Government?* The sanctuary may accept chimpanzees that are not owned by the Federal Government subject to the following conditions:

(1) Ownership of the chimpanzee must be transferred to the sanctuary;

(2) Fees for these chimpanzees may be levied based on a range of considerations that include most importantly, the well-being of the chimpanzee and, secondarily, factors that include (but are not limited to) the resources available to support the chimpanzee; the health, age, and social history of the chimpanzee; and other relevant factors affecting the cost of caring for the chimpanzee. While chimpanzees not owned or supported by the Federal Government may be admitted to the sanctuary, federal funds may not be used for their support unless authorized by the Secretary or an authorized designee;

(3) Available space exists in the sanctuary; and

(4) An agreement exists between the sanctuary system and the NCCR/NIH documenting that the chimpanzee may be brought into the sanctuary.

(d) *What additional conditions apply when nongovernmental owned chimpanzees transfer to the chimpanzee sanctuary?* The following additional conditions apply when nongovernmental owned chimpanzees transfer to the chimpanzee sanctuary:

(1) Chimpanzees transferred to the sanctuary sites must be permanently incapable of reproduction, for example, by vasectomy, tubal ligation, or another reliable procedure;

(2) Complete histories must accompany each chimpanzee. Any chimpanzee missing documentation for any period of research or other use may not be transferred to the Sanctuary without the concurrent authorization of the Sanctuary Contractor's Board of Directors and the NCCR; the records may be created and retained in electronic form; and

(3) Appropriate screening of each chimpanzee must be performed to assess the likelihood of the chimpanzee being a health or safety threat to the care staff and/or other chimpanzees.

(e) *What are the criteria for acceptance and the fees for admission into the sanctuary for nongovernmental owned chimpanzees?* The chimpanzee Sanctuary Contractor, in conjunction with NCCR, must establish criteria and a fee system for acceptance of nongovernmental owned chimpanzees. Funds collected for this purpose must be accounted for and used to help defray the expenses incurred in operating the sanctuary.

(f) *Under what circumstances might a chimpanzee from the sanctuary be returned to research at a United States research facility?* In December 2007, the CHIMP Act was amended by the "Chimp Haven is Home Act," which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes.

#### **§9.6 Animal care, well-being, husbandry, veterinary care, and euthanasia.**

(a) *What are the requirements for promoting the well-being of sanctuary chimpanzees?* The goal of chimpanzee housing and management in the sanctuary is to promote the chimpanzees' well-being.

(b) *What are the provisions for daily chimpanzee husbandry and care?* Adequate and proper care for chimpanzees in the sanctuary must be provided with respect to physical environment, housing and husbandry, behavioral management, and population management and

control. Specific requirements include the following:

(1) Chimpanzees must have access to food, water, and bedding at all times, unless medical or behavioral conditions dictate otherwise. Husbandry procedures shall represent current policies and practices and conform to standards set by a nationally recognized accrediting association in accordance with the *Guide* (incorporated by reference, see paragraph (a) of §9.4).

(2) Indoor primary enclosures must be cleaned as often as required to maintain a clean and healthy environment, with a minimum of once daily. Outdoor enclosures must be monitored daily and cleaned on a routine basis. Outdoor ranging areas will not require a routine cleaning schedule but must be monitored for excessive accumulation of waste or other unhealthy conditions. Housing areas shall provide sufficient space for chimpanzees to perform species-typical behavior and expression. Examples of such activities include but are not limited to natural movements, climbing, swinging, resting, running, group interactions, sleeping, etc. Feeding and watering implements must be sanitized at intervals required to maintain them in a sanitary condition, in accordance with the *Guide* (incorporated by reference, see paragraph (a) of §9.4).

(3) The federally supported chimpanzee sanctuary must employ a behavioral scientist knowledgeable in primate behavior and socialization requirements. This individual shall provide primary leadership in developing, implementing, and monitoring the chimpanzee behavioral guidelines for the sanctuary. Enrichment techniques used shall be currently accepted practices. The sanctuary must provide for the expertise to plan, administer, and evaluate the effectiveness of the well-being program.

(4) Many chimpanzees can be trained through positive reinforcement to cooperate with a variety of veterinary and chimpanzee care procedures. Efforts must be made to develop or maintain this capability for chimpanzees housed in the sanctuary to the extent possible. Trainers must use currently acceptable practices that do not include physical punishment.

(c) *What are the requirements for an adequate veterinary care and animal health program?* The sanctuary staff must provide sufficient resources of personnel, equipment, supplies, and facilities to enable the provision of adequate veterinary care as set forth in the *Guide* (incorporated by reference, see paragraph (b) of §9.4). For additional guidance see the American College of Laboratory Animal Medicine document, "The Provision of Adequate Veterinary Care," available on the Internet at <http://www.aclam.org>.

(1) If the sanctuary houses chimpanzees with infectious diseases, it must have a veterinarian knowledgeable in the infectious diseases and care of chimpanzees. The Facility Veterinarian is responsible for establishing and implementing a health monitoring system specifically designed to meet the health requirements of chimpanzees in the sanctuary. Routine observation and the prevention of disease, metabolic conditions, abnormal behavior and injury must be a priority focus of the Facility Veterinarian and staff.

(2) Newly received chimpanzees must be quarantined for a period for physiological, psychological, and nutritional stabilization before their introduction to the rest of the group. The stabilization period must be lengthened appropriately if the chimpanzee has a significant medical problem or if abnormal medical findings are detected during the quarantine period. If the chimpanzee has not been given a complete physical examination within six months, an examination must be conducted during the stabilization period.

(3) The sanctuary must implement appropriate methods for disease surveillance and diagnosis of diseases, which may include the following:

(4) Tuberculin (TB) tests must be negative for two (2) consecutive tests before the chimpanzee is released from quarantine. Any chimpanzee that is suspected of harboring the TB organism, or that is diagnosed with TB will be isolated and treated until determined by the Facility Veterinarian to be of no health risk to other chimpanzees or humans. The Facility Veterinarian may recommend euthanasia in those cases that do not respond to

therapy and in which the chimpanzee consequently experiences undue pain and suffering that cannot be alleviated. The procedures noted under §9.6 (d) must be observed if euthanasia is necessary.

(5) Fecal samples must be checked for parasites and parasitic ova.

(6) A complete blood count and serum chemical panel must be obtained.

(7) Additional serum for banking and/or testing shall be obtained as appropriate by the Facility Veterinarian and is considered beneficial for chimpanzee health.

(8) If the donating facility did not test for the appropriate viruses, the sanctuary must perform a viral panel and serology for the various chronic hepatitis viruses and HIV.

(9) Additional tests or procedures that are deemed beneficial to the chimpanzees' health may be required by the Facility Veterinarian.

(10) Chimpanzees are susceptible to many of the vaccine preventable diseases of human childhood. Appropriate vaccines must be considered and administered if deemed necessary, at the discretion of the Facility Veterinarian, to protect the chimpanzees in the sanctuary. Methods of disease prevention, diagnosis, and therapy must comply with those currently accepted in veterinary medical practice. Arrangements with diagnostic laboratories must be established before chimpanzees arrive at the sanctuary.

(11) The sanctuary must minimize the use of physical and chemical restraint. Chimpanzees in the sanctuary shall be trained to permit certain procedures with minimal or no restraint. Such procedures may include injections, dosing or other treatments, and cage-side health observations. However, chemical sedation sometimes may be appropriate for certain necessary medical interventions or for the safety of the chimpanzee and caregivers. If physical restraint measures are necessary, due consideration must be given to the temporary or permanent effects upon the chimpanzee and human and animal safety concerns.

(12) Methods used to relieve pain must be documented in the chimpanzee medical or surgical records. These records will be available for review by

USDA and NIH representatives. The Facility Veterinarian must ensure that pain management is current and in accordance with acceptable veterinary medical practices.

(13) Chimpanzees must be cared for by qualified personnel on a daily basis, including weekends and holidays, to safeguard their well-being. Emergency veterinary care must also be available during these times. Notification procedures must be documented in the form of operating procedures.

(d) *Under what circumstances is euthanasia permitted?* As stated in section 481C(d)(2)(I) of the Public Health Service Act, as added by section 2 of the CHIMP Act, none of the chimpanzees may be subjected to euthanasia except when it is in the best interest of the chimpanzee involved as determined by the SCCC and the Facility Veterinarian. Therefore, euthanasia for medical or humane reasons is permitted. Euthanasia may be permitted for reasons of health or quality of life of the individual chimpanzee, including for disease, in connection with trauma, complications of aging, or for other humane reasons. The sanctuary must establish a policy on euthanasia that will provide conditions that must be met before euthanasia is permitted and guidance for performing euthanasia.

(1) Methods of euthanasia will be consistent with the most recent report of the American Veterinary Medical Association Panel on Euthanasia (2002), unless more reliable data becomes available. When euthanasia is performed, the veterinarian will determine the appropriate agent, and it will be administered only by properly trained personnel under the direction of the Facility Veterinarian. The decision to perform euthanasia will be made by the veterinarian in consultation with the Facility Director or Deputy Director.

(2) The SCCC will participate in the decision in nonmedical emergencies. All euthanasia decisions must be reviewed by the SCCC, preferably prior to euthanasia. In emergencies, where euthanasia has to be performed immediately by the Facility Veterinarian, the circumstances and the decision by the Facility Veterinarian will be presented at the next scheduled or special meeting of the SCCC. The NCRR

Project Officer must be notified of the euthanasia event within 72 hours by electronic or telephonic means. Euthanasia of individual chimpanzees may negatively affect the care staff and appropriate counseling and psychological support shall be considered.

#### § 9.7 Reproduction.

Chimpanzee reproduction is prohibited in the sanctuary. Therefore, all males must be sterilized by vasectomy before acceptance into the system, or, as a temporary measure, housed apart from females until they are sterilized. Vasectomies are advisable because they are minimally invasive and because effectiveness of the vasectomy may be validated through laboratory testing for semen. Seminal collection techniques must be carefully evaluated to avoid painful stimuli. Other proven methods of birth control may be used under special conditions deemed appropriate by the Facility Veterinarian and SCCC. The Facility Veterinarian must determine the appropriate test(s) to use to validate sterility. A veterinarian experienced in performing vasectomies in chimpanzees should perform the operation. Documentation must accompany each male accepted to the sanctuary system attesting to the fact that the male has been vasectomized and laboratory tests confirm that a segment of the Vas Deferens has been removed, or that the test used is reliable and is negative for sperm. The sanctuary must have a contingency plan for handling accidental births that includes the length of time the offspring is expected to remain with the mother.

#### § 9.8 Animal records.

(a) *What records must be maintained for chimpanzees in the sanctuary and how are they managed?* (1) Contractors and Subcontractors operating the federal chimpanzee sanctuary system must maintain appropriate records to allow for accountability and disposition of chimpanzees under their care as required by the USDA Animal Welfare Regulations (9 CFR 2.35). The records may be created and retained in electronic form.

(2) The animal records currently required by the USDA Animal Welfare Regulations are also required for these

standards. Chimpanzees must be individually and permanently identifiable.

(3) Retrievable records must be maintained for a minimum of three years beyond the disposition or death of each chimpanzee in accordance with the Animal Welfare Regulations section 2.35(f) (9 CFR 2.35(f)). Original records or a copy must be transferred if the chimpanzee moves to a different facility. The records must include standard information, including permanent individual identification, research use(s), reproductive status (past and present), a summary or copy of the medical and behavioral history, the sire's identification number (if available), the dam's identification number, birth date, sex, and date acquired by the sanctuary. The disposition date must also be noted, if applicable, including whether the chimpanzee died or was transferred to another site in the federal sanctuary system. The records may be created and retained in electronic form.

(4) The contractor and any subcontractor(s) operating the federally supported chimpanzee sanctuary must provide special, quarterly, and annual progress reports to the designated Federal officials as identified in the contract. The annual report must also contain a statement that certifies the sanctuary is in full compliance with these standards of care regulation.

(b) *What are the rules governing the disposition of necropsy records?* The CHIMP Act requires that necropsy records from chimpanzees previously used in federally funded research projects be made available on a reasonable basis to investigators engaged in biomedical or behavioral research. In order to comply with this provision, the contractor for the sanctuary system must devise a plan that will allow interested parties to contact the sanctuary and receive necropsy records when they become available. Records may be provided free of charge but requesters may be required to pay for packaging and shipping costs. The records may be created and retained in electronic form.

#### § 9.9 Facility staffing.

*How many personnel are required to staff the chimpanzee sanctuary and what*

*qualifications and training must the staff possess?* (a) The professional, managerial, and support staff must be sufficient to support the scope and diversity of the activities and chimpanzee population of the sanctuary. The level of staffing shall be adequate to ensure that the chimpanzees receive appropriate health care, are well cared for, and the administrative and fiscal operations are sound and in keeping with current practices required by NCRR/NIH;

(b) There must be a sufficient number of appropriately trained animal care and technical personnel to provide appropriate care to the chimpanzees at all times, including evenings, weekends, and holidays. The number of animal care staff to chimpanzee ratio shall be adjusted as experience is gained during the operation of the sanctuary. Sufficiently trained staff also must be available to maintain adequate behavioral enrichment;

(c) The Facility Director must be a person with experience in chimpanzee care and socialization techniques. In addition, the Director must have management and administrative experience;

(d) The Biosafety Officer must have experience in developing and monitoring biohazards and dealing with biosafety issues related to captive nonhuman primates. Experience in these areas dealing specifically with chimpanzees is desirable;

(e) The remaining staff, which may include part-time, full-time, or contractor Facility Veterinarian(s) and Behaviorist(s), must possess the skills, knowledge, and/or experience required to perform their duties, as elaborated within the regulation.

**§9.10 Occupational Health and Safety Program (OHSP) and biosafety requirements.**

(a) *How are employee Occupational Health and Safety Program risks and concerns addressed?* The sanctuary shall assure that an Occupational Health and Safety Program (OHSP) is developed and implemented in accordance with current veterinary medical practices and the guidelines and standards found in the *Guide* (incorporated by reference, see paragraph (a) of section 9.4);

(b) *How are biosafety concerns addressed?* The sanctuary shall institute and administer an effective biosafety program that addresses the biosafety hazards at that particular site. The program shall include identifying biohazards, outlining practices and procedures to be followed, providing personal safety equipment or protective clothing and equipment, and establishing a description of the facility requirements for working with hazardous agents or materials. Policies and procedures must be implemented to avoid exposure to environmental and animal hazards. Biosafety must be included in the training program for all Sanctuary employees. In establishing a program, the Sanctuary must use current accepted practices and publications prepared by the CDC, NIH, and professional societies specializing in biosafety. The input and guidance of personnel trained or experienced in biosafety are essential. Complete records of both clinical and experimental agent exposure must accompany each chimpanzee sent to the sanctuary. The donating facility must also provide recent testing (for example, serology, virus culture, histology) so that the sanctuary staff is fully aware of the health condition of the arriving chimpanzee. The records may be created and retained in electronic form.

**§9.11 Animal transport.**

The transportation of chimpanzees by surface or air must be in accordance with the requirements set forth in the Animal Welfare Act and Regulations and the International Air Transport Association (IATA) Live Animal Regulations and guidelines, as applicable.

**§9.12 Compliance with the Standards of Care, and USDA and PHS policies and regulations.**

(a) *How will compliance with the standards set forth in this part be monitored and what are the consequences of non-compliance with the standards?* The federally supported chimpanzee sanctuary must comply with the standards of care set forth in this part and include a statement in the Annual Progress Report certifying compliance with these standards of care in accordance with the terms of the current contract



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between NCRR and the Sanctuary Contractor. A designated representative of the Secretary will monitor compliance. The responsibility to monitor compliance with the standards is delegated to NCRR/NIH/HHS. The NIH/NCRR Project Officer for this contract will conduct scheduled site visits at least one time annually (or more often if necessary) and review monthly and quarterly reports submitted to the Project and Contract Officer. Subcontractors are subjected to the same provisions. Failure to comply with the standards set forth in this part, or to correct deficiencies noted within the allowable time period, could result in termination of the contract by the Federal Government (HHS/NIH), or allow the Secretary to correct the deficiencies according to the terms and conditions outlined in the contract. The Secretary may impose additional sanctions on the contractor up to, and including, authorizing assumption or reassignment of the management of the sanctuary contract.

(b) *To what type of outside review or inspection will the federally supported sanctuary be subjected?* As noted in paragraph (a) of this section, the contractor for the sanctuary will be monitored on a regularly scheduled basis

by representatives of NCRR/NIH/HHS. The NCRR representative will use facility site visits, reports, personal contact, and any other means as appropriate to ensure compliance with these standards. The contractor and subcontractors are required to obtain and maintain an Animal Welfare Assurance from NIH's Office of Laboratory Animal Welfare (OLAW) when chimpanzees are used for noninvasive studies as authorized in the CHIMP Act. In addition, the sanctuary must achieve accreditation by a nationally recognized animal program accrediting body (such as the AAALAC, the AZA, or similar recognized body) within a time frame to be determined by NCRR/NIH. The federally supported sanctuary must comply with the requirements set forth in the Animal Welfare Regulations (9 CFR parts 1 through 3).

### **§ 9.13 Other federal laws, regulations, and statutes that apply to the sanctuary.**

(a) Animal Welfare Act (7 U.S.C. 2131–2159).

(b) Animal Welfare Regulations, 9 CFR, subchapter A, parts 1 and 2; part 3, subpart D—Specifications for the Humane Handling, Care, Treatment, and Transport of Nonhuman Primates.